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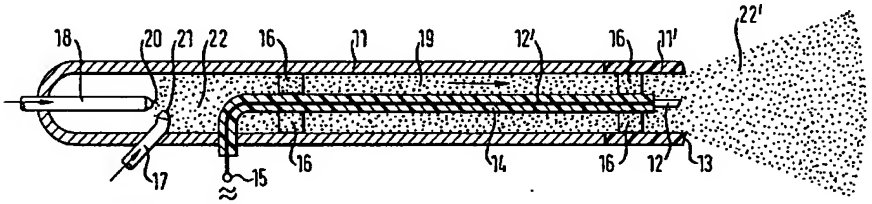
(54) Elektrochirurgische Vorrichtung zur Erzeugung eines Lichtbogens

(57) Die Erfindung betrifft eine elektrochirurgische Vorrichtung zur berührungslosen Oberflächenkoagulation von Biogewebe mittels einer Hochfrequenz-Schneidelektrode 12. Zur Schaffung einer ionisierten Strecke für die erleichterte Lichtbogenbildung wird in einem rohrförmigen Instrumentenkörper 11 ein Aerosolstrahl 20 gebildet, der aus dem distalen Ende 13 des Instrumentenkörpers 11 austritt.

FIG. 1



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Beschreibung

Die Erfindung betrifft ein Verfahren nach dem Oberbegriff des Patentanspruchs 1 und eine elektrochirurgische Vorrichtung nach dem Oberbegriff des Anspruches 7.

Bei stark durchblutetem Biogewebe besteht häufig das Erfordernis, unter Verwendung der Hochfrequenz-Chirurgie Gewebeoberflächen berührungslos und gleichmäßig zu koagulieren. Konventionell wird dies mit der sogenannten Sprüh-Koagulation bzw. Spray-Koagulation bei hohen Hochfrequenzspannungen im Bereich von Kilovolt bewerkstelligt. Ein Nachteil dieser konventionellen Technik ist die Unregelmäßigkeit des Lichtbogenbereichs und die Gefahr, die Gewebeoberfläche zu karbonisieren.

Eine Verbesserung wurde dadurch erzielt, daß durch Einblasen eines Edelgases z. B. von Argon ein Ionisierungspfad geschaffen wurde, der zur Verbesserung der Gleichmäßigkeit bei der Koagulation von Gewebeoberflächen beitrug. Ein derartiges Verfahren ist z. B. in der EP 0 353 177 A1 beschrieben. Nachteil dieses Verfahrens ist die Verwendung des recht teuren und in Kliniken häufig nicht verfügbaren Edelgases.

Das Ziel der vorliegenden Erfindung besteht darin, ein Verfahren und eine Vorrichtung der eingangs genannten Gattung zu schaffen, mittels denen ein Ionisierungspfad im Bereich der aktiven Elektrode mit einfacheren Maßnahmen zur Verfügung gestellt wird.

Zur Lösung dieser Aufgabe sind die Merkmale der Patentansprüche 1 und 7 vorgesehen.

Der Erfindung liegt der Grundgedanke zugrunde, daß ein Ionisierungspfad auch mit anderen Medien als Edelgasen möglich ist. Als vorteilhaft hat sich hierbei die Erzeugung eines Aerosols aus einer niederprozentigen Kochsalzlösung herausgestellt. Die Kombination von Hochfrequenz an der aktiven Elektrode einer elektro-chirurgischen Vorrichtung mit einer NaCl-Lösung ist zwar bekannt, doch wurde diese bisher nur verwendet, um ein Ankleben der Elektroden am Biogewebe zu verhindern.

Erfindungsgemäß wird dem gegenüber ein Aerosol mit einem gewissen Spüldruck von z. B. 3,5 bar um die Elektrode herumgespült bzw. herumgeblasen, wodurch ein Ionisierungskegel mit definierter Dimensionierung entsteht.

Als positive Effekte des erfindungsgemäßen Verfahrens ergeben sich die Verwendung von verfügbaren Medien, z. B. destilliertem Wasser, CO_2, NaCl-Lösung, eine gleichmäßige Koagulation des Biogewebes in einer festumgrenzten Fläche, eine geringe Gefahr einer Karbonisierung, eine Kühlung der Elektrode, keine, sonst übliche Rauchbildung und keinerlei Geruchsbildung durch Verbrennen von Gewebe.

Vorteilhafte Ausführungen des erfindungsgemäßen Verfahrens sind durch die Ansprüche 2 bis 6 und vorteilhafte Ausführungsformen der erfindungsgemäßen Vorrichtung durch die Ansprüche 8 bis 10 gekennzeichnet.

Die Erfindung wird im folgenden beispielsweise anhand der Zeichnung beschrieben; in dieser zeigt

Figur 1 einen schematischen Schnitt einer rein beispielsweisen Ausführungsform einer erfindungsgemäßen elektrochirurgischen Vorrichtung zur Erzeugung eines Aerosolstrahls um eine hochfrequenz-chirurgische Schneidelektrode herum.

In einem von der Hand des Benutzers ergreifbaren hohlzylinderförmigen Instrumentenkörper 11 ist koaxial eine hochfrequenz-chirurgische Schneidelektrode 12 angeordnet, die gegenüber dem distalen offenen Ende 13 des rohrförmigen Instrumentenkörpers 11 ein Stück zurückversetzt ist und mit einer Zuleitung 12' verbunden ist, die sich - von einer Isolierung 14 umgeben - mit allseitigem Abstand von der Innenwand des rohrförmigen Instrumentenkörpers 11 nach hinten erstreckt, wo im Bereich des proximalen Endes seitlich ein Hochfrequenzanschluß 15 vorgesehen ist, an den eine geeignete Hochfrequenzspannung, die von einem nicht dargestellten Hochfrequenzgenerator erzeugt wird, anlegbar ist. Die zugehörige Neutralelektrode ist an geeigneter Stelle des Patientenkörpers angeordnet. Der distale Bereich des im übrigen aus Metall bestehenden Instrumentenkörpers 11 ist aus einem isolierenden Material 11' hergestellt, welches sich nach hinten bis über die Isolierung 14 der Zuleitung 12' erstreckt.

Die Zuleitung 12' mit der Isolierung 14 wird durch geeignete Halterungen 16 vorzugsweise koaxial innerhalb des Instrumentenkörpers 11 gehalten. Die einzelnen Halterungen 16 sind jeweils über den Umfang um die Isolierung 14 herum mit solchem Abstand angeordnet, daß dazwischen in axialer Richtung ein ausreichend dimensionierter Strömungsdurchgang vorliegt.

Am proximalen Ende des Instrumentenkörpers 11 sind seitlich bzw. axial zwei Zufuhrrohre 17, 18 in das Innere des Instrumentenkörpers 11 hineingeführt. An das Rohr 17 wird eine Leitung angeschlossen, mittels derer beispielsweise eine 0,9 %-ige Kochsalzlösung zugeführt wird. Das axial eingeführte Rohr 18 ist an einen Druckluftanschluß angelegt, so daß es mit Druckluft als Trägergas beaufschlagt werden kann.

Innerhalb des Hohlraumes 19 des Instrumentenkörpers 11 weisen die Rohre 17, 18 Öffnungen 20, 21 auf, durch welche die Kochsalzlösung bzw. die Luft so in den Innenraum 19 hineingedrückt werden, daß es zu einer Zerstäubung der Kochsalzlösung kommt, d. h. zur Bildung eines Aerosols 20, welches aufgrund des Druckaufbaus insbesondere durch das Rohr 18 in Richtung des Pfeiles durch den Instrumentenkörper 11 zum distalen Ende 13 hin strömt und dort als kegelförmig erweiterndes Aerosolbündel bzw. Aerosolstrahl 22' austritt, welches bzw. welcher somit die Spitze der Schneidelektrode 12 und das von dieser zu koagulierende Biogewebe umgibt. Durch die hohe Spannung der Schneidelektrode 12 wird das Aerosol ionisiert und somit eine ionisierte Strecke zwischen Schneidelek-

trode 12 und Biogewebe gebildet, auf der sich dann ein besonders gleichmäßiger und damit auch besonders gut lokalisierbarer Lichtbogen ausbildet.

Das Druckluft-Zufuhrrohr 18 ist derart weit axial in das Innere des Instrumentenkörpers 11 hineingeführt, daß seine Austrittsdüse 20 sich unmittelbar oberhalb und etwas hinter der quer verlaufenden Austrittsdüse 21 des Flüssigkeits-Zufuhrrohres 17 befindet. Auf diese Weise saugt die über die Austrittsdüse 21 strömende Luft Flüssigkeit aus dem Rohr 17 an und zerstäubt sie gleichzeitig zur Bildung des Aerosols 22.

Statt der durch die Rohre 17, 18 gebildeten Zerstäubungsvorrichtung könnte auch ein Ultraschallvernebler am bzw. im Instrumentenkörper 11 oder in einem Abstand von diesem vorgesehen sein. Im letzteren Fall wäre der Ultraschallvernebler über einen Aerosol-Zuleitungsschlauch mit dem Inneren des Instrumentenkörpers 11 zu verbinden.

Patentansprüche

1. Verfahren zur berührungslosen Oberflächenkoagulation von Biogewebe mittels eines Lichtbogens, der durch die von einem Hochfrequenzgenerator erzeugte Hochspannung an einem hochfrequenzchirurgischen Instrument erzeugt wird,
   dadurch **gekennzeichnet,**
   daß zur Schaffung einer ionisierten Strecke für die erleichterte Lichtbogenbildung ein unter Verwendung einer Flüssigkeit und eines Trägergases gebildeter Aerosolstrahl in die Region, wo der Lichtbogen sich bilden soll und sich eine an einer Hochfrequenzspannung angelegte Elektrode (12) befindet, geschickt wird.

2. Verfahren nach Anspruch 1,
   dadurch **gekennzeichnet,**
   daß dem Aerosolstrahl zur Verbesserung der Leitfähigkeit Ionen, z. B. NaCl oder KJ, beigemischt werden.

3. Verfahren nach Anspruch 1 oder 2,
   dadurch **gekennzeichnet,**
   daß der Aerosolstrahl durch eine 0,9 %-ige Kochsalzlösung gebildet wird.

4. Verfahren nach einem der vorhergehenden Ansprüche,
   dadurch **gekennzeichnet,**
   daß das Aerosol nach dem Zerstäuberprinzip und insbesondere durch einen wie ein Vergaser ausgebildeten Zerstäuber erzeugt wird.

5. Verfahren nach einem der Ansprüche 1 bis 3,
   dadurch **gekennzeichnet,**
   daß das Aerosol durch einen Ultraschallvernebler erzeugt wird.

6. Verfahren nach einem der vorhergehenden Ansprüche,
   dadurch **gekennzeichnet,**
   daß als Trägergas für die Bildung des Aerosols, d. h. für die Zerstäubung der im Aerosol enthaltenen Flüssigkeit Luft und/oder Kohlendioxid und/oder Stickstoff verwendet wird, wobei bevorzugt der Vordruck des Trägergases einstellbar ist.

7. Elektrochirurgische Vorrichtung mit einer an eine von einem Hochfrequenzgenerator erzeugte Hochfrequenzspannung anlegbaren Aktivelektrode (12) und einer Neutralelektrode zur Erzeugung eines Lichtbogens im Biogewebe zwecks berührungsmoser Oberflächenkoagulation, insbesondere zur Ausführung des Verfahrens nach einem der Ansprüche 1 bis 6,
   dadurch **gekennzeichnet,**
   daß sie eine Aerosolstrahl-Bildungkomponente (17,18,19) aufweist, welche einen unter Verwendung eines Trägergases und einer Flüssigkeit gebildeten Aerosolstrahl in den Bereich um die aktive Elektrode (12) schickt, wo der Lichtbogen gebildet werden soll.

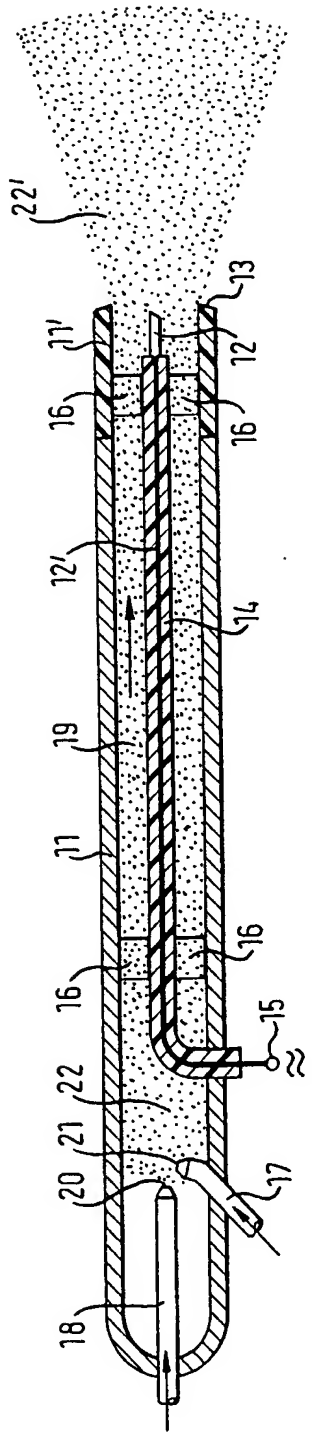
8. Vorrichtung nach Anspruch 7,
   dadurch **gekennzeichnet,**
   daß die Aerosolstrahl-Erzeugungskomponente einen Zerstäuberkanal (19) mit einer Austrittsdüse (13) aufweist und/oder daß die Aerosolstrahl-Erzeugungskomponente einen Ultraschallvernebler umfaßt, der wahlweise im Handgriff (11) oder außerhalb des Handgriffs angeordnet und durch eine Schlauchverbindung mit dem Handgriff (11) verbunden ist und/oder daß die aktive Hochfrequenzelektrode (12) vorzugsweise mittig im Zerstäuber- bzw. Ultraschallnebelkanal (19) angeordnet ist und/oder daß die Zerstäuber-/Vernebler-Elektrodenanordnung in ein und demselben Handgriff (11) untergebracht ist, wobei der bzw. die Hochfrequenzanschlüsse (15) und die Trägergas-Flüssigkeitsanschlüsse (17, 18) ebenfalls am Handgriff (11) vorgesehen sind.

9. Vorrichtung nach Anspruch 7 oder 8,
   dadurch **gekennzeichnet,**
   daß die aktive Elektrode (12) gegenüber der Austrittsdüse (13) des Instrumentenkörpers (11) etwas zurückversetzt ist und/oder daß die aktive Elektrode (12) nadel- oder stabartig ausgebildet ist und/oder daß der distale Bereich des Instrumentenkörpers (11) aus Isoliermaterial (11') besteht.

10. Vorrichtung nach einem der Ansprüche 7 bis 9,
    dadurch **gekennzeichnet,**
    daß die aktive Elektrode (12) an eine sich im Instrumentenkörper (11) längs erstreckende Hochfrequenz-Zuleitung (12') angeschlossen ist, die von einer Isolierung (14) umgeben ist und/oder daß

zwischen der Zuleitung (12') zur aktiven Elektrode (12) bzw. der Isolation (14) der Zuleitung (12') und der Innenwand des Instrumentenkörpers (11) vorzugsweise isolierende Abstandshalter (16) derart angeordnet sind, daß zwischen an einer bestimmten axialen Stelle des Instrumentenkörpers (11) angeordneten Abstandshaltern (16) ausreichend Platz für den axialen Durchgang des Aerosols vorhanden ist.

FIG. 1



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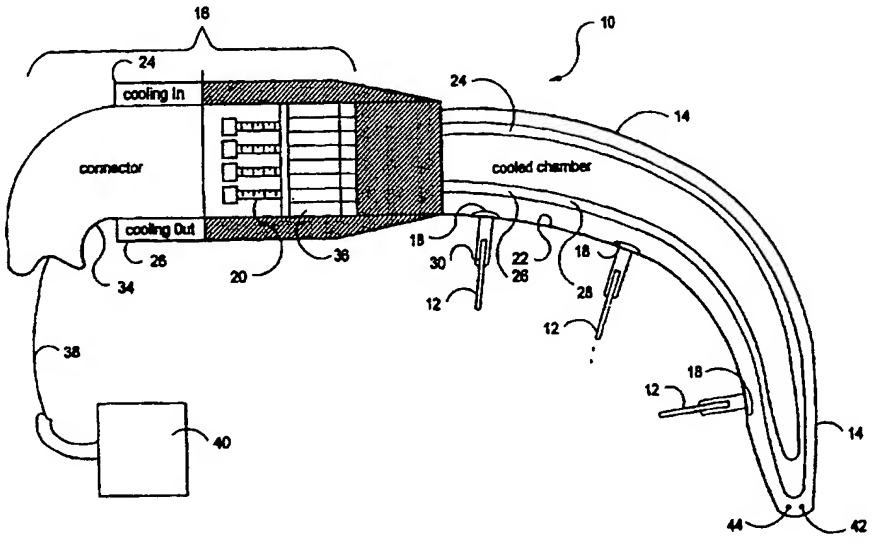

(57) Abstract

A method for cosmetically remodeling the tongue provides a source of ablation energy and an ablation energy delivery device. At least a portion of the ablation energy delivery device is advanced into an interior of the tongue. A sufficient amount of energy is delivered from the energy delivery device into the interior of the tongue to debulk a section of the tongue without damaging a hypoglossal nerve. Thereafter, the ablation energy delivery device is retracted from the interior of the tongue. The treatment is indicated in the therapy to prevent sleep apnoea, or heavy snoring.

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APPARATUS FOR COSMETICALLY REMODELING A BODY STRUCTURE

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to a method for maintaining upper airway patency in human patients, and more particularly to a method which utilizes electromagnetic energy to debulk selected sections of the tongue and/or lingual tonsil without damaging the hypoglossal nerve.

Description of Related Art

Sleep-apnea syndrome is a medical condition characterized by daytime hypersomnomulence, morning arm aches, intellectual deterioration, cardiac arrhythmias, snoring and thrashing during sleep. It is caused by frequent episodes of apnea during the patient's sleep. The syndrome is classically subdivided into two types. One type, termed "central sleep apnea syndrome", is characterized by repeated loss of respiratory effort. The second type, termed obstructive sleep apnea syndrome, is characterized by repeated apneic episodes during sleep resulting from obstruction of the patient's upper airway or that portion of the patient's respiratory tract which is cephalad to, and does not include, the larynx.

Treatment thus far includes various medical, surgical and physical measures. Medical measures include the use of medications such as protriptyline, medroxyprogesterone, acetazolamide, theophylline, nicotine and other medications in addition to avoidance of central nervous system depressants such as sedatives or alcohol. The medical measures above are sometimes helpful but are rarely completely effective. Further, the medications frequently have undesirable side effects.

Surgical interventions have included uvulopalatopharyngoplasty, tonsillectomy, surgery to correct severe retrognathia and tracheostomy. In one procedure the jaw is dislodged and pulled forward, in order to gain access to the

base of the tongue. These procedures may be effective but the risk of surgery in these patients can be prohibitive and the procedures are often unacceptable to the patients.

Physical measures have included weight loss, nasopharyngeal airways, nasal CPAP and various tongue retaining devices used nocturnally. These measures may be partially effective but are cumbersome, uncomfortable and patients often will not continue to use these for prolonged periods of time. Weight loss may be effective but is rarely achieved by these patients.

In patients with central sleep apnea syndrome, phrenic nerve or diaphragmatic pacing has been used. Phrenic nerve or diaphragmatic pacing includes the use of electrical stimulation to regulate and control the patient's diaphragm which is innervated bilaterally by the phrenic nerves to assist or support ventilation. This pacing is disclosed in *Direct Diaphragm Stimulation* by J. Mugica et al. PACE vol. 10 Jan-Feb. 1987, Part II, *Preliminary Test of a Muscular Diaphragm Pacing System on Human Patients* by J. Mugica et al. from Neurostimulation: An Overview 1985 pp. 263-279 and *Electrical Activation of Respiration* by Nochomovitez IEEE Eng. in Medicine and Biology; June, 1993.

However, it was found that many of these patients also have some degree of obstructive sleep apnea which worsens when the inspiratory force is augmented by the pacer. The ventilation induced by the activation of the diaphragm also collapses the upper airway upon inspiration and draws the patient's tongue inferiorly down the throat choking the patient. These patients then require tracheostomies for adequate treatment.

A physiological laryngeal pacemaker as described in *Physiological Laryngeal Pacemaker* by F. Kaneko et al. from Trans Am Soc Artif Intern Organs 1985 senses volume displaced by the lungs and stimulates the appropriate nerve to open the patient's glottis to treat dyspnea. This apparatus is not effective for treatment of sleep apnea. The apparatus produces a signal proportional in the displaced air volume of the lungs and thereby the signal

produced is too late to be used as an indicator for the treatment of sleep apnea. There is often no displaced air volume in sleep apnea due to obstruction.

One measure that is effective in obstructive sleep apnea is tracheostomy. However, this surgical intervention carries considerable morbidity and is aesthetically unacceptable to many patients. Other surgical procedures include pulling the tongue as forward as possible and surgically cutting and removing sections of the tongue and other structures which can close off the upper airway passage.

There is a need for a method and apparatus to overcome these problems.

SUMMARY OF THE INVENTION

Accordingly, an object of the invention is to provide a method for cosmetically remodeling a tongue.

Another object of the invention is to provide a method for cosmetically remodeling a tongue without damaging a hypoglossal nerve of the tongue.

Still another object of the invention is to provide a method for cosmetically remodeling a tongue with reduced swelling of the tongue.

A further object of the invention is to provide a method for cosmetically remodeling a tongue by applying ablative energy to a selected site in an interior of the tongue without damaging a hypoglossal nerve of the tongue.

Still a further object of the invention is to provide a method for cosmetically remodeling a tongue by applying an ablative agent to a selected site in an interior of the tongue without damaging a hypoglossal nerve of the tongue.

Another object of the invention is to provide a method for cosmetically remodeling a lingual tonsil.

These and other objects of the invention are achieved in a method for cosmetically remodeling the tongue. An ablation apparatus is provided that includes a source of ablation energy and an ablation energy delivery device. At least a portion of the ablation energy delivery device is advanced into an interior of the tongue. A sufficient amount of energy is delivered from the energy delivery device into the interior of the tongue to debulk a section of the tongue

without damaging a hypoglossal nerve. Thereafter, the ablation energy delivery device is retracted from the interior of the tongue.

In another embodiment, an ablative agent source is provided. The ablative agent source is coupled to an ablative agent delivery device. At least a portion of the ablative agent delivery device is advanced into an interior of the tongue. A sufficient amount of an ablative agent is delivered from the ablative agent delivery device into the interior of the tongue to debulk a section of the tongue without damaging a hypoglossal nerve. Thereafter, the ablative agent delivery device is retracted from the interior of the tongue.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 is a cross-sectional view of an ablation apparatus used with the methods of the present invention.

Figure 2 is cross-sectional view illustrating the catheter and connector of the ablation apparatus shown in Figure 1.

Figure 3 is a perspective view of the connector illustrated in Figure 1.

Figure 4 is a perspective view of a needle electrode associated with the ablation apparatus illustrated in Figure 1.

Figure 5 is a perspective view of a flexible needle electrode utilized with the methods of the present invention.

Figure 6 illustrates the creation of ablation zones with the ablation apparatus shown in Figure 1.

Figure 7 is a cross-sectional view of the tongue with the mouth closed.

Figure 8 is a cross-sectional view of the tongue with the mouth open.

Figure 9 is a perspective view of the tongue.

Figure 10 is a perspective view of the dorsum of the tongue.

Figure 11 is a cross-sectional view of the tongue.

Figure 12 is a cross-sectional view of the tongue illustrating the location of the hypoglossal nerves and the creation of an ablation zone.

Figure 13 is a cross-sectional view of the tongue illustrating a plurality of ablation zones.

Figure 14 is a perspective view of the ventral surface of the tongue.

Figure 15 is a cross-sectional view of the tongue.

Figure 16 is a block diagram illustrating an analog amplifier, analog multiplexer and microprocessor used with the feedback control system.

Figure 17 is a block diagram of a temperature/impedance feedback system that can be used to control cooling medium flow rate through the catheter of Figure 1.

Figure 18 is a block diagram of a temperature/impedance feedback system that can be used to control cooling medium flow rate through the catheter of Figure 1.

Figure 19 is a three dimensional graph illustrating the percent shrinkage of the tongue following RF ablation.

Figure 20 is a graph illustrating two-dimensional shrinkage of bovine tongue tissue with RF ablation.

Figure 21 is a graph illustrating three-dimensional shrinkage of bovine tongue tissue due to RF ablation.

Figure 22 is a graph illustrating percent volume change in a tongue following RF ablation.

DETAILED DESCRIPTION

A method for cosmetically remodeling and debulking the tongue, uvula, soft palate, lingual tonsil and/or adenoids provides an ablation apparatus including a source of electromagnetic energy and one or more electromagnetic energy delivery electrodes coupled to the electromagnetic energy source. At least one electrode is advanced into an interior of the tongue. Sufficient electromagnetic energy is delivered from the electrode to debulk a section of the tongue without damaging the hypoglossal nerve. The electrode is then removed from the interior of the tongue. A method for treating airway obstructions is achieved by debulking the tongue without damaging the hypoglossal nerve. The electrode can be introduced into the tongue from the tongue's tip, ventral surface, dorsum, underneath the tongue, along the tongue's midline, or in certain

instances through the chin area. The tongue is ablated (debulked) without damaging the hypoglossal nerves, resulting in a remodeling of the tongue and a cosmetic change. This is achieved by positioning the electrodes far enough away from the hypoglossal nerves so that during the delivery of electromagnetic energy to the tongue, the hypoglossal nerves are not damaged. Another method for treating airway obstructions is achieved by debulking the lingual tonsil without damaging the hypoglossal nerve. These methods are used to treat sleep apnea.

Referring to Figures 1 and 2, an ablation apparatus 10 for cosmetically remodeling and debulking the tongue, lingual tonsils, uvula, soft palate and/or adenoids is illustrated. Ablation apparatus 10 can be positioned so that one or more energy delivery devices or electrodes 12 are introduced into an interior of the tongue through the tongue. Ablation apparatus 10 may include atraumatic intubation with or without visualization, provide for the delivery of oxygen or anesthetics, and can be capable of suctioning blood or other secretions. It will be appreciated that ablation apparatus 10 is used to treat a variety of different obstructions in the body where passage of gas is restricted. One embodiment is the treatment of sleep apnea using electrodes 12 to ablate (cell necrosis) selected portions of the tongue, lingual tonsils and/or adenoids by the use of resistive heating, RF, microwave, ultrasound and liquid thermal jet. The preferred energy source is an RF source. In this regard, ablation apparatus 10 can be used to ablate targeted masses including but not limited to the tongue, tonsils, turbinates, soft palate tissues, hard tissue and mucosal tissue. In one embodiment, ablation apparatus 10 is used to debulk the tongue in order to increase the cross-sectional area of the air passageway. A disinfectant medium introduction member introduces a disinfectant medium in the oral cavity in order to reduce infection of the ablated body member.

Prior to debulking the tongue, a presurgical evaluation may be performed including a physical examination, fiberoptic pharyngoscopy, cephalometric analysis and polygraphic monitoring. The physical examination emphasizes the evaluation of the head and neck. It also includes a close examination of the nasal

cavity to identify obstructing deformities of the septum and turbinate; oropharyngeal obstruction from a long, redundant soft palate or hypertrophic tonsils; and hypopharyngeal obstruction from a prominent base of the tongue.

Debulking apparatus 10 includes a catheter 14, an optional handle 16 and one or more electrodes 12 extending from different ports 18 formed along a longitudinal surface of catheter 14, or from a distal end of electrode 12. Catheter 14 can be a handpiece. An advancement device 20 may be provided. Advancement device 20 can include guide tracks or tubes 23 positioned in the interior of catheter 14. Electrodes 12 may be positioned in guide tracks 23 and advanced from guide tracks into the interior of the tongue.

Ablation or debulking apparatus 10 includes a catheter 14, an optional handle 16 and one or more ablation source delivery device 12 extending from different ports 18 formed along a longitudinal surface of catheter 14, or from a distal portion of ablation source delivery device 12 Catheter 14 can be a handpiece. Ablation source delivery device advancement device 20, also known as advancement device 20 may be provided. Ablation source delivery device advancement device 20 can include guide tracks or tubes 23 positioned in the interior of catheter 14. Ablation source delivery device 12 may be positioned in guide tracks 23 and advanced from the guide tracks into the interior of the tongue. Cabling is coupled to ablation source delivery device 12.

Ablation source delivery device 12 may be least partially positioned in an interior of catheter 14. In one embodiment, ablation source delivery device 12 is advanced and retracted through a port 18 formed in an exterior surface of catheter 14. Ablation source delivery device advancement and retraction device 20 advances ablation source delivery device 12 out of catheter 14, into an interior of a body structure and can also provide a retraction of ablation source delivery device 12 from the interior of the body structure. Although the body structure can be any number of different structures, the body structure will hereafter be referred to as the tongue. Ablation source delivery device 12 pierce an exterior surface of the tongue and are directed to an interior region of the tongue. Sufficient ablation energy is delivered by ablation source 12 to the

interior of the tongue to cause the tongue to become sufficiently ablated and debulked. Ablation source delivery device 12 can be a hollow structure that is, (i) adapted to deliver different chemicals to a selected tongue interior ablation site (for chemical ablation) (ii) deliver alcohol or other liquids or semi-liquids to achieve ablation as well as a variety of different infusion mediums, including but not limited to saline, chemotherapy and the like. Different modalities can be combined to achieved a desired ablation including but not limited to RF and chemotherapy, chemical and chemotherapy. Ablation source delivery device 12 may have a limited travel distance in the tongue. In one embodiment with RF electrodes, this is achieved with an insulation sleeve that is in a surrounding relationship to an exterior of an electrode. Other devices can include a structure located on ablation source delivery device 12 which limits their advancement, or a structure coupled to a catheter which limits the advancement of ablation source delivery devices 12, such as a stop and the like. One suitable fluid is an electrolytic solution. Instead of direct contact with tissue and electrode 12 for the delivery of thermal energy, a cooled electrolytic solution can be used to deliver the thermal energy to the tissue. The electrolytic solution may be cooled in the range of about 30 to 55 degrees C.

Catheter 14 includes a catheter tissue interface surface 22, a cooling medium inlet conduit 24 and a cooling medium exit conduit 26 extending through an interior of catheter 14. Ports 18 are formed in the exterior of catheter 14, and are preferably formed on catheter tissue interface surface 22. Ports 18 are isolated from a cooling medium flowing in inlet and outlet conduits 24 and 26. Cooling medium inlet and exit conduits 24 and 26 are configured to provide a cooled section of catheter tissue interface surface 22 of at least 1 to 2 cm^2. More preferably, the cooled section of catheter tissue interface surface 22 is at least equal to the cross-sectional diameter of the underlying zone of ablation.

In one embodiment, the cooled section of catheter tissue interface surface 22 is at least equal to the cross-sectional diameter of the underlying zone of ablation. In another embodiment, the cooled section of catheter tissue interface

surface 22 only provides cooling to an area associated with each deployed ablation source delivery device.

The size of the cooled section of catheter tissue interface surface 22 varies for each patient. The size is sufficient enough to minimize swelling of the tongue following the delivery of electromagnetic energy. The reduction of swelling can be 50% or greater, 75% or greater , and 90% and greater. The amount of cooling provided is sufficient to enable the patient to return home shortly after the debulking procedure is performed, and not run the risk of choking on the tongue. It has been found that by providing a sufficient level of cooling over a relatively large area, the amount of ablation in an interior region of the tongue is enhanced. By providing a sufficiently large enough cooled section of catheter tissue interface surface 22, an adenomas response is minimized.

Handle 16 is preferably made of an insulating material. Electrodes 12 are made of a conductive material such as stainless steel. Additionally, electrodes 12 can be made of a shaped memory metal, such as nickel titanium, commercially available from Raychem Corporation, Menlo Park, California. In one embodiment, only a distal end of electrode 12 is made of the shaped memory metal in order to effect a desired deflection. When introduced into the oral cavity, catheter 14 can be advanced until a patient's gag response is initiated. Catheter 14 is then retracted back to prevent patient's gagging. The distal end of electrode 12 can be semi-curved. The distal end can have a geometry to conform to an exterior of the tongue.

In one embodiment of the invention catheter 14 is a handpiece. In this embodiment, a separate handle 16 is not necessary. Debulking apparatus 10 is used to treat an interior region of the tongue. Catheter 14 has a distal end that is sized to be positioned within an oral cavity. Ablation source delivery device 12 is at least partially positioned within an interior of catheter 14. Ablation source delivery device 12 includes ablation delivery surface 30. Ablation source delivery device 20 is coupled to ablation source delivery device 12 and calibrated to advance ablation source delivery device 12 from catheter 14, including but not

limited to a distal position of catheter 14, into the interior of the tongue when catheter 14 is positioned adjacent to a surface of the tongue. Ablation source delivery device 12 is advanced an advancement distance 33 from catheter 14 of sufficient length to treat the interior region of the tongue with ablation energy and/or an ablation effect without damaging the hypoglossal nerve or the surface of the tongue.

Catheter 14 can be malleable in order to conform to the surface of the tongue when a selected ablation target site is selected. An encapsulated soft metal, such as copper, or an annealed metal/plastic material can be used to form malleable catheter 14. All or a portion of catheter 14 may be malleable or made of a shaped memory metal.

For many applications it is desirable for a distal end 14' of catheter 14 to be deflectable. This can be achieved mechanically or with the use of memory metals. A steering wire, or other mechanical structure, can be attached to either the exterior or interior of distal end 14'. In one embodiment, a deflection knob located on handle 16 is activated by the physician causing a steering wire to tighten. This imparts a retraction of distal end 14', resulting in its deflection. It will be appreciated that other mechanical devices can be used in place of the steering wire. The deflection may be desirable for tissue sites with difficult access.

Controlled volumetric reduction of the tongue, under feedback control is used to achieve an effective opening in the airway passage. A variety of different pain killing medicaments, including but not limited to Xylocaine, may be used. A digital ultrasonic measurement system can be used. The ultrasound measurement quantifies biological shape changes, provides ultrasonic transmission and reception, uses piezoelectric transducers (crystals) and provides time of flight data.

A disinfectant medium introduction member 21 may also be introduced into the oral cavity. The disinfectant medium can be introduced prior to ablation, during ablation and/or after the ablation. It can be delivered continuously. The level of disinfection of the oral cavity is selectable as the

volume of the oral cavity that is disinfected. The degree of disinfection varies. Disinfection is provided to reduce infection of the ablated body structure. Disinfectant medium introduction member 21 can be introduced before, after or during the introduction of ablation apparatus 10 into the oral cavity. Additionally, disinfectant medium introduction member 21 can be removed at the same time or at a different time that ablation apparatus 10 is removed from the oral cavity.

Disinfectant medium introduction member 21 can be included in ablation apparatus 10, in an interior of catheter 14 or at an exterior of catheter 14, and may be an introducer with a lumen configured to introduce a disinfectant agent from a disinfectant agent source 23 into all or a selected portion of the oral cavity. Disinfectant medium introduction member 21 can be capable of movement within the oral cavity in order to provide for disinfection of all or only a portion of the oral cavity. For purposes of this disclosure, the oral cavity is that body internal environment where infectious germs may be introduced into the ablated tongue, soft tissue structure, and the like. Disinfectant medium introduction member 21 may be slideably positioned in catheter 14 or at its exterior. Alternatively, disinfectant medium introduction member 21 can be an optical fiber coupled to a light energy source, including but not limited to a UV source 25. The optical fiber can also be slideably be positioned in the oral cavity. The optical fiber is configured to provide for the selective disinfection of all or only a portion of the oral cavity and can have a variety of different distal ends to achieve this purpose.

Suitable disinfectant agents include but are not limited to Peridex, an oral rinse containing 0.12% chlorhexidine glucinate (1, 1'-hexanethylenebis[5-(p-chlorophenyl) biganide} di-D-gluconate in a base containing water, 11.6% alcohol, glycerin, PEG 40 sorbitan arisoterate, flavor, dosium saccharin, and FD&C Blue No. 1.

It will be appreciated that a variety of different disinfectants can be employed, including other electromagnetic wavelengths, and various chemical compositions.

Electrodes 12 are at least partially positioned in an interior of catheter 14. Each electrode 12 is advanced and retracted through a port 18 formed in an exterior surface of catheter 14. Advancement and retraction device advances electrodes 12 out of catheter 14, into an interior of a body structure and retracted back into catheter 14. Electrodes 12 pierce an exterior surface of the tongue and are directed to an interior region of the tongue. Sufficient electromagnetic energy is delivered by electrodes 12 to the interior of the tongue to cause the tongue to become sufficiently ablated and debulked. Electrodes 12 can be hollow to receive a variety of different infusion mediums, including but not limited to saline. Electrodes 12 may be limited in the distance that they can be advanced into the tongue. This is achieved with an insulation sleeve, a structure located on electrodes 12 which limits their advancement, or a structure coupled to catheter which limits the advancement of electrodes 12, such as a stop and the like.

The disinfectant medium can be introduced prior to ablation, during ablation and/or after the ablation. It can be delivered continuously. The level of disinfection of the oral cavity is selectable as is the volume of the oral cavity that is disinfected. The degree of disinfection varies. Disinfection is provided to reduce infection of the ablated body structure.

An ablation delivery surface, such as an electromagnetic energy delivery surface 30 of electrode 12 can be adjusted by inclusion of an adjustable or non-adjustable insulation sleeve 32 (Figures 3, 4, and 5). Insulation sleeve 32 can be advanced and retracted along the exterior surface of electrode 12 in order to increase or decrease the length of the electromagnetic energy delivery surface 30. Insulation sleeve 32 can be made of a variety of materials including but not limited to nylon, polyimides, other thermoplastics and the like. The size of electromagnetic energy delivery surface 30 can be varied by other methods including but not limited to creating a segmented electrode with a plurality of electrodes that are capable of being multiplexed and individually activated, and the like.

Referring specifically to Figure 4, ablation source delivery device 12 has an advancement length 33 that extends from an exterior surface of catheter 14 and is directed into the interior of the tongue. Advancement length 33 is sufficient to position ablation delivery surface 30 at a selected tissue site in the interior of the tongue. Ablation delivery surface 30 is of sufficient length so that the ablation effect is delivered to the selected tissue site, create a desired level of ablation at the selected tissue site without causing damage to the hypoglossal nerve. Ablation delivery surface 30 is not always at the distal end of ablation source delivery device 12. Insulation 32 can also be positioned at the distal end of ablation source delivery device 12. In this embodiment, ablation delivery surface 30 does not extend to the distal end of ablation source delivery device 12. However, ablation delivery surface 30 still delivers a sufficient ablation effect to create a desired level of cell necrosis in the interior of the tongue at the selected tissue site without damaging the hypoglossal nerve and/or damage to the surface of the tongue. Additionally, only one side or a portion of a side of ablation source delivery device 12 can be insulated. This also provides for an ablation source delivery device 12 which can be positioned throughout the tongue, including adjacent to a hypoglossal nerve. Where ablation source delivery device 12 is adjacent to the hypoglossal nerve, ablation source delivery device 12 is insulated.

In one embodiment, advancement length 33 is 1.2 to 1.5 cm, and the length of ablation delivery surface 30 is 5 to 10 mm, more preferably about 8 mm.

In another embodiment, advancement length 33 is insufficient to reach the hypoglossal nerve when introduced through any of the tongue surfaces, particularly the dorsum of the tongue.

Advancement device 20 is configured to advance at least a portion of each ablation source delivery device 12 to a placement position in the interior of the tongue. Advancement device 20 can also be configured to retract each ablation source delivery device 12. At the placement position, ablation delivery surface delivers sufficient ablation energy and/or effect to reduce a volume of the

selected site without damaging a hypoglossal nerve and/or a surface of the tongue. In one embodiment, ablation source delivery device advancement and retraction device 20, with or without guide tracks 23, directs the delivery of ablation source delivery device 12 from catheter 14 into the interior of the tongue at an angle of 60 to 90 degrees relative to a longitudinal axis of catheter 14, and preferably about 70 degrees.

In certain embodiments, ablation source delivery device 12 has a geometric shape, including but not limited to a curved configuration that includes one or more insulated surfaces, either partially insulated on one side, at a proximal end, at a distal end, and the like, that is configured to reduce the volume of the selected tissue site without damaging a hypoglossal nerve. In one embodiment, ablation source delivery device 12 is introduced through any tongue surface and is configured so that a section of ablation source delivery device 12 which may be positioned close to the hypoglossal nerve is provided with insulation 32. As previously noted, insulation 32 can be positioned at different sites of ablation source delivery device 12.

Handle 16 can comprise a connector 34 coupled to retraction and advancement device 20. Connector 34 provides a coupling of electrodes 12 to power, feedback control, temperature and/or imaging systems. An RF/temperature control block 36 can be included.

In one embodiment, the physician moves retraction and advancement device 20 in a direction toward a distal end of connector 34. Electrodes 12 can be spring loaded. When retraction and advancement device 20 is moved back, springs cause selected electrodes 12 to advance out of catheter 14.

One or more cables 38 couple electrodes 12 to an electromagnetic energy source 40. A variety of energy sources 40 can be used with the present invention to transfer electromagnetic energy to the interior of a body structure, including but not limited to RF, microwave, ultrasound, coherent light and thermal transfer. Preferably, energy source 40 is a RF generator. When a RF energy source is used, the physician can activate RF energy source 40 by the use of a foot switch (not shown) coupled to RF energy source 40.

One or more sensors 42 may be positioned on an interior or exterior surface of electrode 12, insulation sleeve 32, or be independently inserted into the interior of the body structure. Sensors 42 permit accurate measurement of temperature at a tissue site in order to determine, (i) the extent of ablation, (ii) the amount of ablation, (iii) whether or not further ablation is needed, and (iv) the boundary or periphery of the ablated geometry. Further, sensors 42 prevent non-targeted tissue from being destroyed or ablated.

Sensors 42 are of conventional design, including but not limited to thermistors, thermocouples, resistive wires, and the like. Suitable sensors 42 include a T type thermocouple with copper constantene, J type, E type, K type, fiber optics, resistive wires, thermocouple IR detectors, and the like. It will be appreciated that sensors 42 need not be thermal sensors.

Sensors 42 measure temperature and/or impedance to permit ablation monitoring. This reduces damage to tissue surrounding the targeted ablation mass. By monitoring the temperature at various points within the interior of the body structure the periphery of ablation can be ascertained and it is possible to determine when the ablation is completed. If at any time sensor 42 determines that a desired ablation temperature is exceeded, then an appropriate feedback signal is received at energy source 40 and the amount of energy delivered is regulated.

Ablation or debulking apparatus 10 can include visualization capability including but not limited to a viewing scope, an expanded eyepiece, fiber optics, video imaging, and the like.

Additionally, ultrasound imaging can be used to position the electrodes 12 and/or determine the amount of ablation. One or more ultrasound transducers 44 can be positioned in or on electrode 12, catheter 14, or on a separate device. An imaging probe may also be used internally or externally to the selected tissue site. A suitable imaging probe is Model 21362, manufactured and sold by Hewlett Packard Company. Each ultrasound transducer 44 is coupled to an ultrasound source (not shown).

With reference now to Figure 6 catheter 14 is shown as being introduced into the oral cavity and multiple RF electrodes 12 are advanced into the interior of the tongue creating different ablation zones 46. Using RF, ablation apparatus 10 can be operated in either bipolar or monopolar modes. In Figure 6, electrodes 12 are operated in the bipolar mode, creating sufficient ablation zones 46 to debulk the tongue without affecting the hypoglossal nerves and creating a larger airway passage. With this debulking, the back of the tongue moves in a forward direction away from the air passageway. The result is an increase in the cross-sectional diameter of the air passageway.

Using RF, ablation apparatus 10 can also be operated in the monopolar mode. A groundpad can be positioned in a convenient place such as under the chin. A single electrode 12 is positioned in the tongue to create a first ablation zone 46. Electrode 12 can then be retracted from the interior of the tongue, catheter 14 moved, and electrode 12 is then advanced from catheter 14 into another interior section of the tongue. A second ablation zone 46 is created. This procedure can be completed any number of times to form different ablation regions in the interior of the tongue. More than one electrode 12 can be introduced into the tongue and operated in the bipolar mode. Electrodes 12 are then repositioned in the interior of the tongue any number of times to create a plurality of connecting or non-connecting ablation zones 46.

Referring now to Figures 7 through 15, various anatomical views of the tongue and other structures are illustrated. The different anatomical structures are as follows: the genioglossus muscle, or body of the tongue is denoted as 48; the geniohyoid muscle is 50; the mylohyoid muscle is 52; the hyoid bone is 54; the tip of the tongue is 56; the ventral surface of the tongue is denoted as 58; the dorsum of the tongue is denoted as 60; the inferior dorsal of the tongue is denoted as 62; the reflex of the vallecula is 64; the lingual follicles are denoted as 66; the uvula is 68; the adenoid area is 70; the lateral border of the tongue is 72; the circumvallate papilla is 74, the palatine tonsil is 76; the pharynx is 78; the redundant pharyngeal tissue is 80; the foramen cecum is 82; the hypoglossal nerve is 84, and the lingual frenum of the tongue is 86.

Dorsum 60 is divided into an anterior 2/3 and inferior dorsal 62. The delineation is determined by circumvallate papilla 74 and foramen cecum 82. Inferior dorsal 62 is the dorsal surface inferior to circumvallate papilla 74 and superior reflex of the vallecula 64. Reflex of the vallecula 64 is the deepest portion of the surface of the tongue contiguous with the epiglottis. Lingual follicles 66 comprise the lingual tonsil.

Catheter 14 can be introduced through the nose or through the oral cavity. Electrodes 12 can be inserted into an interior of the tongue through dorsum surface 60, inferior dorsal surface 62, ventral surface 58, tip 56 or geniohyoid muscle 50. Additionally, electrodes may be introduced into an interior of lingual follicles 66 and into adenoid area 70. Once electrodes 12 are positioned, insulation sleeve 32 may be adjusted to provided a desired electromagnetic energy delivery surface 30 for each electrode 12.

Ablation zones 46 are created without damaging hypoglossal nerves 84. This creates a larger air way passage and provides a treatment for sleep apnea.

In all instances, the positioning of electrodes 12, as well as the creation of ablation zones 46 is such that hypoglossal nerves 84 are not ablated or damaged. The ability to swallow and speak is not impaired.

In one embodiment, RF electrode 12 are placed on the dorsum surface of the tongue. The first electrode is positioned 0.5 cm proximal to the circumvallate pappilla. The other electrodes are spaced 1.6 cm apart and are 1 cm off a central axis of the tongue. In one embodiment, 465 MHz RF was applied. The temperature at the distal end of electrode 12 was about 100 degrees C. The temperature at the distal end of the insulation sleeve 32 was about 60 degrees C. In another embodiment, the temperature at the distal end of insulation sleeve 32 was 43 degrees C and above. RF energy can be applied as short duration pulses with low frequency RF. Precise targeting of a desired ablation site is achieved. One or more electrodes 12 may be used to create volumetric three-dimensional ablation. A variety of ablation geometries are possible, including but not limited to rectilinear, polyhedral, redetermined shapes, symmetrical and non-symmetrical.

Referring now to Figures 16 and 17 an open or closed loop feedback system couples sensors 42 to energy source 40. The temperature of the tissue, or of electrode 12 is monitored, and the output power of energy source 40 adjusted accordingly. Additionally, the level of disinfection in the oral cavity can be monitored. The physician can, if desired, override the closed or open loop system. A microprocessor can be included and incorporated in the closed or open loop system to switch power on and off, as well as modulate the power. The closed loop system utilizes a microprocessor 88 to serve as a controller, watch the temperature, adjust the RF power, look at the result, refeed the result, and then modulate the power.

With the use of sensors 42 and the feedback control system a tissue adjacent to RF electrodes 12 can be maintained at a desired temperature for a selected period of time without impeding out. Each RF electrode 12 is connected to resources which generate an independent output for each RF electrode 12. An output maintains a selected energy at RF electrodes 12 for a selected length of time.

When an RF electrode is used, current delivered through RF electrodes 12 is measured by current sensor 90. Voltage is measured by voltage sensor 92. Impedance and power are then calculated at power and impedance calculation device 94. These values can then be displayed at user interface and display 96. Signals representative of power and impedance values are received by a controller 98.

A control signal is generated by controller 98 that is proportional to the difference between an actual measured value, and a desired value. The control signal is used by power circuits 100 to adjust the power output in an appropriate amount in order to maintain the desired power delivered at respective RF electrodes 12.

In a similar manner, temperatures detected at sensors 42 provide feedback for maintaining a selected power. The actual temperatures are measured at temperature measurement device 102, and the temperatures are displayed at user interface and display 96. A control signal is generated by

controller 98 that is proportional to the difference between an actual measured temperature, and a desired temperature. The control signal is used by power circuits 100 to adjust the power output in an appropriate amount in order to maintain the desired temperature delivered at the respective sensor. A multiplexer can be included to measure current, voltage and temperature, at the numerous sensors 42, and energy can be delivered to RF electrodes 12 in monopolar or bipolar fashion.

Controller 98 can be a digital or analog controller, or a computer with software. When controller 98 is a computer it can include a CPU coupled through a system bus. On this system can be a keyboard, a disk drive, or other non-volatile memory systems, a display, and other peripherals, as are known in the art. Also coupled to the bus is a program memory and a data memory.

User interface and display 96 includes operator controls and a display. Controller 98 can be coupled to imaging systems, including but not limited to ultrasound, CT scanners, X-ray, MRI, mammographic X-ray and the like. Further, direct visualization and tactile imaging can be utilized.

The output of current sensor 90 and voltage sensor 92 is used by controller 98 to maintain a selected power level at RF electrodes 12. The amount of RF energy delivered controls the amount of power. A profile of power delivered can be incorporated in controller 98, and a preset amount of energy to be delivered can also be profiled. Other sensors similar to sensors 90 and 92 can be used by controller 98 for other ablation source delivery devices 12 to maintain a controllable amount of an ablation energy and/or ablative agent.

Circuitry, software and feedback to controller 98 result in process control, and the maintenance of the selected power that is independent of changes in voltage or current, and are used to change, (i) the selected power, (ii) the duty cycle (on-off and wattage), (iii) bipolar or monopolar energy delivery, and (iv) infusion medium delivery, including flow rate and pressure. These process variables are controlled and varied, while maintaining the desired delivery of power independent of changes in voltage or current, based on temperatures monitored at sensors 42.

Current sensor 90 and voltage sensor 92 are connected to the input of an analog amplifier 104. Analog amplifier 104 can be a conventional differential amplifier circuit for use with sensors 42. The output of analog amplifier 104 is sequentially connected by an analog multiplexer 106 to the input of A/D converter 108. The output of analog amplifier 104 is a voltage which represents the respective sensed temperatures. Digitized amplifier output voltages are supplied by A/D converter 108 to microprocessor 88. Microprocessor 88 may be a type 68HCII available from Motorola. However, it will be appreciated that any suitable microprocessor or general purpose digital or analog computer can be used to calculate impedance or temperature.

Microprocessor 88 sequentially receives and stores digital representations of impedance and temperature. Each digital value received by microprocessor 88 corresponds to different temperatures and impedances.

Calculated power and impedance values can be indicated on user interface and display 96. Alternatively, or in addition to the numerical indication of power or impedance, calculated impedance and power values can be compared by microprocessor 88 with power and impedance limits. When the values exceed predetermined power or impedance values, a warning can be given on user interface and display 96, and additionally, the delivery of RF energy can be reduced, modified or interrupted. A control signal from microprocessor 88 can modify the power level supplied by energy source 40.

Figure 18 illustrates a block diagram of a temperature/impedance feedback system that can be used to control cooling medium flow rate through catheter 14. Electromagnetic energy is delivered to electrode 12 by energy source 44, and applied to tissue. A monitor 110 ascertains tissue impedance, based on the energy delivered to tissue, and compares the measured impedance value to a set value. If the measured impedance exceeds the set value a disabling signal 112 is transmitted to energy source 40, ceasing further delivery of energy to electrode 12. If measured impedance is within acceptable limits, energy continues to be applied to the tissue. During the application of energy to tissue sensor 42 measures the temperature of tissue and/or electrode 12. A comparator

114 receives a signal representative of the measured temperature and compares this value to a pre-set signal representative of the desired temperature. Comparator 114 sends a signal to a flow regulator 116 representing a need for a higher cooling medium flow rate, if the tissue temperature is too high, or to maintain the flow rate if the temperature has not exceeded the desired temperature.

EXAMPLE 1

Ablation apparatus 10 was used to determine two-dimensional shrinkage of a bovine. RF volumetric reduction was achieved using a single needle electrode. Four miniature ultrasonic crystals were positioned to form a square. Measurements were taken at control and post volumetric reduction at 15 watts initially with a 13% volumetric reduction, and 15 watts for 4 hours with an additional 4% volumetric reduction. A total 17% volumetric reduction was achieved.

EXAMPLE 2

Ablation apparatus 10 was used to determine three-dimensional shrinkage of a bovine tongue. RF volumetric reduction was achieved with a single needle electrode with eight miniature ultrasonic crystals, creating a cube. Application of 16 watts initially produced a 17% volumetric reduction of the tongue, 25 watts applied initially produced a 25% volumetric reduction, and 25 watts after hours produced an additional 4% reduction, for a total volumetric reduction of 29%.

EXAMPLE 3

A 35% volumetric reduction was achieved in porcine in vivo, with three dimensional gross at 20 watts initial application.

Referring now to Figure 19, ablation volume dimensions were measured with a multidimensional digital sonomicrometry. An average decrease in the Z direction was 20%, and volume shrinkage was 26%. Three-dimensional shrinkage of tongue tissue due to *in vivo* RF ablation with the needle, ablation with 20 Watts) is presented in Figure 20. Control volume before ablation is compared with a post-ablation volume.

Figure 20 illustrates two-dimensional shrinkage of a bovine tongue tissue due to RF ablation with a needle electrode. The before and after ablation results are illustrated.

Figure 21 illustrates in graph form ablation at 16 Watts resulted in a 17% volume shrinkage of the tissue in post-ablation verses control. Ablation at 25 watts resulted in a 25% volume shrinkage after ablation. An additional 4% area shrinkage was obtained after in long-term post ablation (4 hours) verses post-ablation.

Figure 22 illustrates a percent volume change after RF ablation. 16 Watts, ablation at 16 Watts for 20 minutes; 25 Watts, ablation at 25 Watts for 20 minutes; 25 Watts (4 hours), and long tern post ablation (4 hours after 25 Watts ablation).

The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this art. It is intended that the scope of the invention be defined by the following claims and their equivalents.

What is claimed is:

CLAIMS

1. A method for cosmetically remodeling a tongue, comprising:

providing an ablation apparatus including a source of electromagnetic energy and one or more electromagnetic energy delivery electrodes coupled to the electromagnetic energy source;

advancing at least one electrode into an interior of the tongue;

delivering a sufficient amount of electromagnetic energy from the electrode into the interior of the tongue to debulk a section of the tongue and remodel the tongue without damaging the hypoglossal nerve; and

retracting the electrode from the interior of the tongue.

2. The method of claim 1, wherein the energy source is an RF source.

3. The method of claim 1, wherein the energy source is a microwave source.

4. The method of claim 1, wherein the electrode is advanced into an interior of the tongue through a ventral surface of the tongue.

5. The method of claim 1, wherein the electrode is advanced into an interior of the tongue through an inferior dorsal surface of the tongue.

6. The method of claim 1, wherein the electrode is advanced into an interior of the tongue through a dorsum surface of the tongue.

7. The method of claim 1, wherein the electrode is advanced into an interior of the tongue through a tip of the tongue.

8. The method of claim 1, wherein two or more electrodes are advanced into a different interior area of the tongue.

9. The method of claim 1, wherein two or more electrodes are introduced through a different surface site of the tongue.

10. The method of claim 1, wherein the ablation apparatus further comprises:

a catheter including a lumen, wherein the electrode is deployed from the catheter lumen into an interior of the tongue.

11. The method of claim 1, wherein the catheter further comprises:

a cooling element.

12. The method of claim 11, wherein the cooling element comprises a cooling channel in an interior of the catheter, the cooling channel receiving a cooling medium and circulating the cooling medium through the interior of the catheter.

13. The method of claim 12, further comprising:

cooling a surface of the tongue while an electrode ablates an interior section of the tongue.

14. The method of claim 10, wherein the catheter is introduced into an oral cavity and one or more electrodes are introduced into an interior of the tongue through one of an inferior dorsal surface of the tongue, a dorsum surface of the tongue, or a tip of the tongue.

15. The method of claim 10, wherein the catheter is introduced into an oral cavity and one or more electrodes are introduced into an interior of the tongue through a ventral surface of the tongue.

16. The method of claim 1, further comprising:

providing an imaging apparatus.

17. The method of claim 16, wherein the imaging apparatus is an ultrasound device.

18. The method of claim 16, further comprising:

imaging the tongue prior to debulking the tongue.

19. The method of claim 16, further comprising:

imaging the tongue after debulking the tongue.

20. A method for cosmetically remodeling a lingual tonsil, comprising:

providing an ablation apparatus including a source of electromagnetic energy and one or more electromagnetic energy delivery electrodes coupled to the electromagnetic energy source,;

advancing at least one electrode into a lingual tonsil;

delivering sufficient electromagnetic energy from the electrode into an interior of the lingual tonsil to debulk and remodel the lingual tonsil; and

retracting the electrode from the lingual tonsil.

21. The method of claim 20, wherein the energy source is an RF source.

22. The method of claim 20, wherein one or more electrodes are advanced into a different section of the lingual tonsil.

23. The method of claim 20, further comprising:

providing an imaging apparatus.

24. The method of claim 23, wherein the imaging apparatus is an ultrasound device.

25. The method of claim 23, further comprising:
imaging the lingual tonsil prior to debulking.

26. The method of claim 23, further comprising:
imaging the lingual tonsil after debulking.

27. A method for cosmetically remodeling a tongue, comprising:
providing an ablation apparatus including a source of ablation energy and an ablation energy delivery device;
advancing at least a portion of the ablation energy delivery device into an interior of the tongue;
delivering a sufficient amount of energy from the energy delivery device into the interior of the tongue to debulk a section of the tongue and remodel the tongue without damaging a hypoglossal nerve; and
retracting the ablation energy delivery device from the interior of the tongue.

28. The method of claim 27, wherein the energy source is an RF source and the ablation energy delivery device is an RF electrode.

29. The method of claim 27, wherein the energy source is a coherent source of light and the ablation energy delivery device is an optical fiber.

30. The method of claim 27, wherein the energy source is a heated fluid and the ablation energy delivery device is a catheter with a closed channel configured to receive the heated fluid.

31. The method of claim 27, wherein the energy source is a heated fluid and the ablation energy delivery device is a catheter with an open channel configured to receive the heated fluid.

32. The method of claim 27, wherein the energy source is a cooled fluid and the ablation energy delivery device is a catheter with a closed channel configured to receive the cooled fluid.

33. The method of claim 27, wherein the energy source is a cooled fluid and the ablation energy delivery device is a catheter with an open channel configured to receive the cooled fluid.

34. The method of claim 27, wherein the energy source is a cryogenic fluid.

35. The apparatus of claim 27, wherein the energy source is a microwave source providing energy from 915 MHz to 2.45 GHz and the ablation energy delivery device is a microwave antenna.

36. The apparatus of claim 27, wherein the energy source is an ultrasound source and the ablation energy delivery device is an ultrasound emitter.

37. The method of claim 27, wherein the energy source is a microwave source.

38. The method of claim 27, wherein the electrode is advanced into an interior of the tongue through a ventral surface of the tongue.

39. The method of claim 27, wherein the ablation energy delivery device is advanced into an interior of the tongue through an inferior dorsal surface of the tongue.

40. The method of claim 27, wherein the ablation energy delivery device is advanced into an interior of the tongue through a dorsum surface of the tongue.

41. The method of claim 27, wherein the ablation energy delivery device is advanced into an interior of the tongue through a tip of the tongue.

42. A method for cosmetically remodeling a tongue, comprising:

providing an ablative agent source coupled to an ablative agent delivery device;

advancing at least a portion of the ablative agent delivery device into an interior of the tongue;

delivering a sufficient amount of an ablative agent from the ablative agent delivery device into the interior of the tongue to debulk a section of the tongue and remodel the tongue without damaging a hypoglossal nerve; and

retracting the ablative agent delivery device from the interior of the tongue.

43. The method of claim 42, wherein the ablative agent is a chemical composition or mixture of compositions.

44. The method of claim 42, wherein the ablative agent includes an alcohol composition.

45. The method of claim 42, wherein the ablative agent is a chemotherapeutic agent.

46. The method of claim 45, further comprising:

providing an RF electrode to deliver electromagnetic energy to an interior section of the tongue.

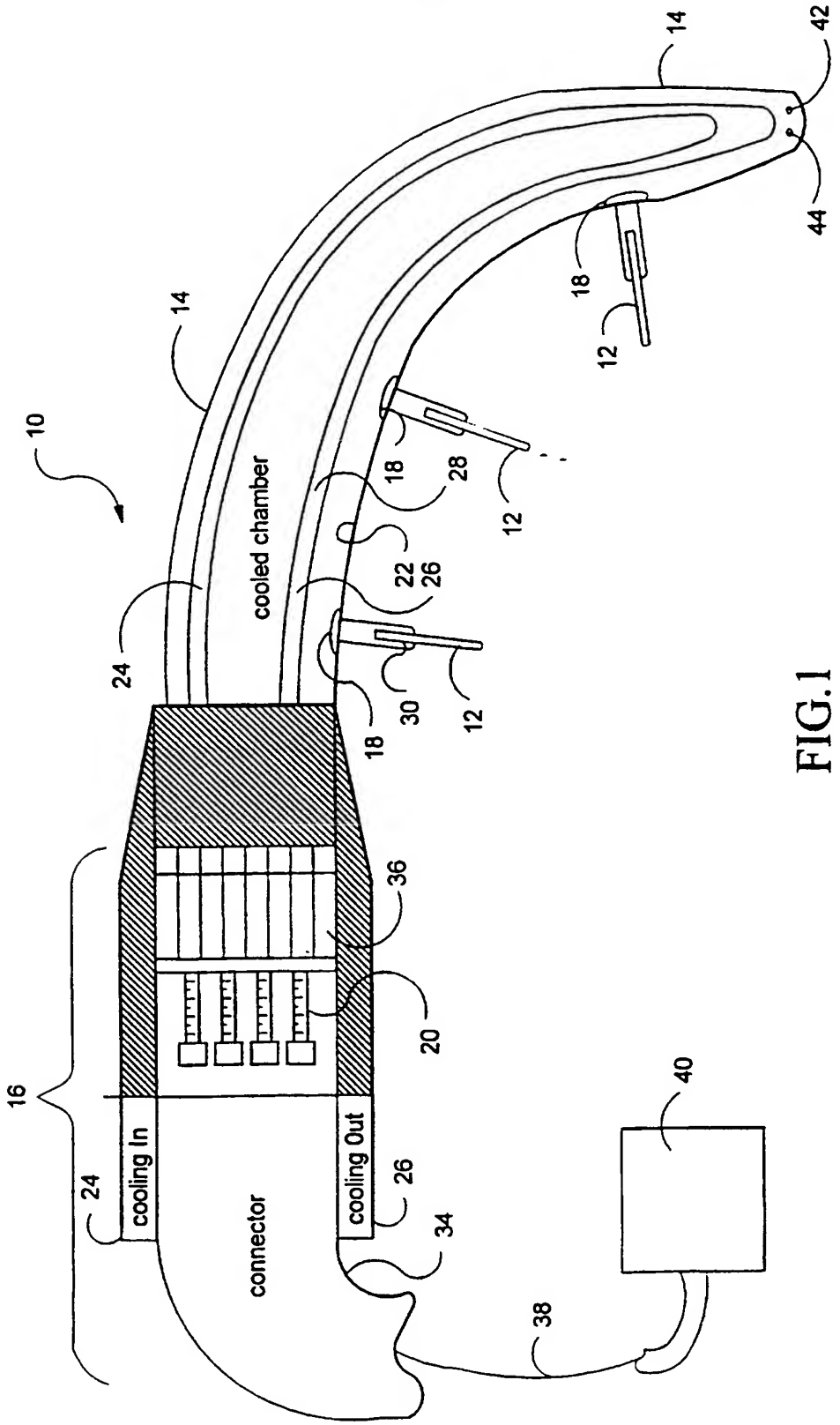

14
42
44
18
12
14
10
cooled chamber
18
28
12
22
26
24
30
18
12
36
20
16
40
24
cooling In
connector
cooling Out
26
34
38

FIG.1

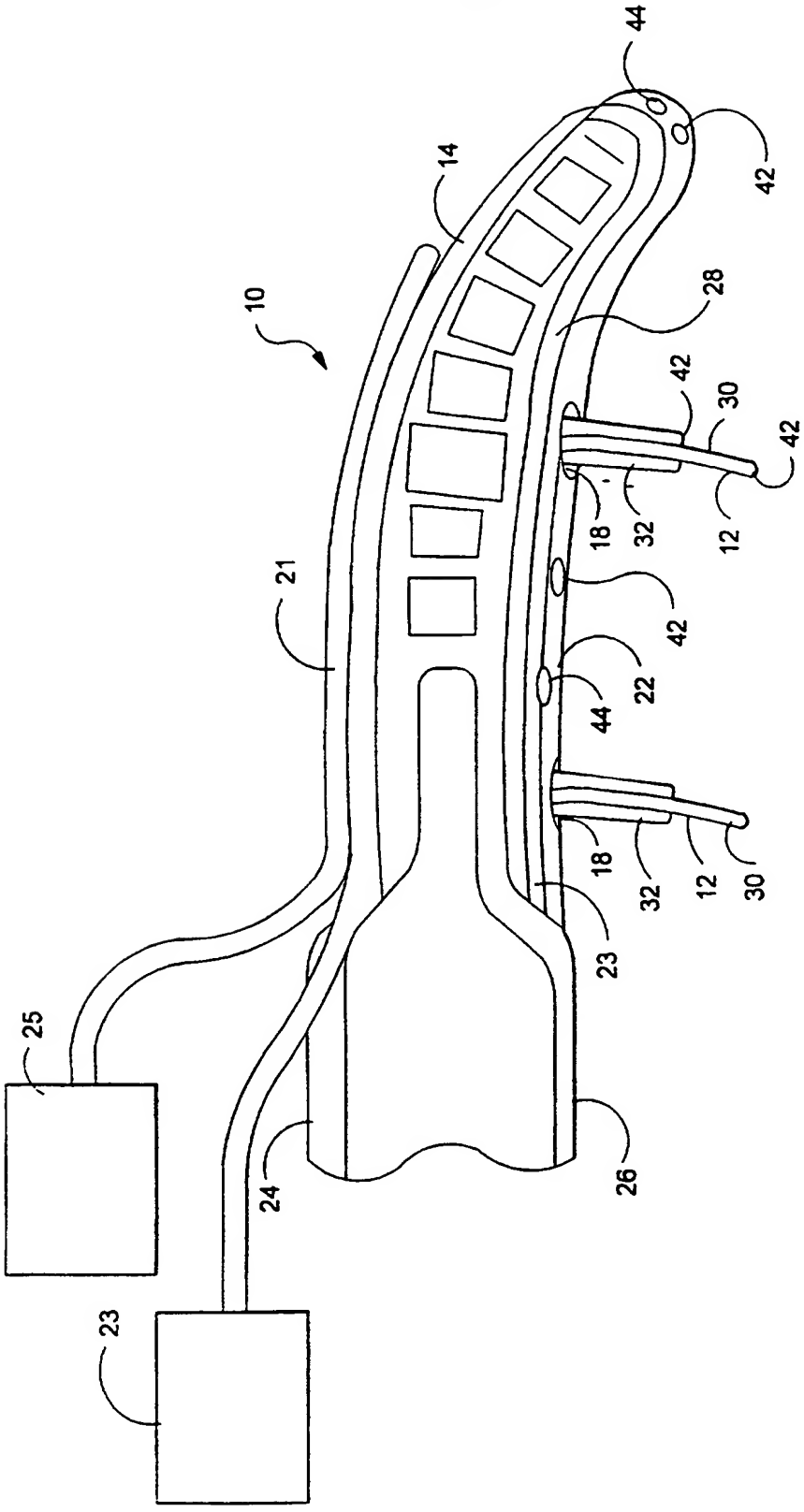
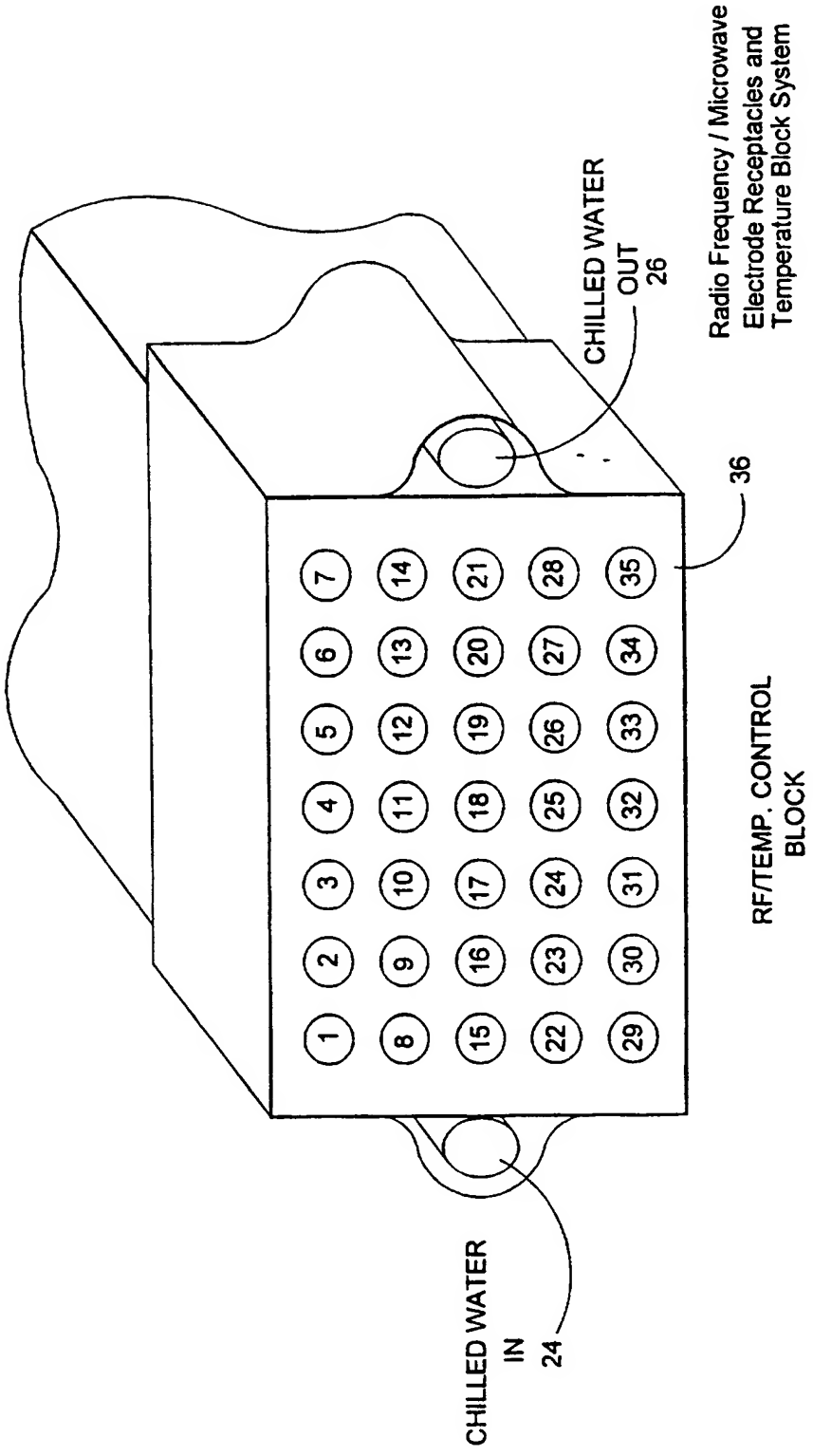


FIG.2


Radio Frequency / Microwave
Electrode Receptacles and
Temperature Block System
CHILLED WATER
OUT
26
36
RF/TEMP. CONTROL
BLOCK
CHILLED WATER
IN
24
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
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34
35

FIG.3

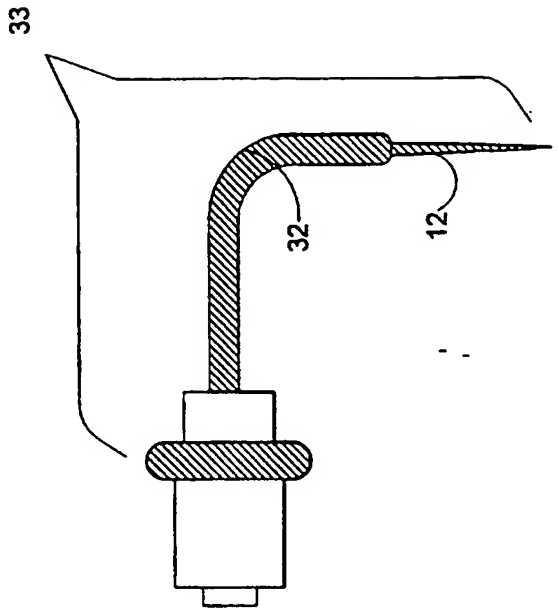

FIG.5

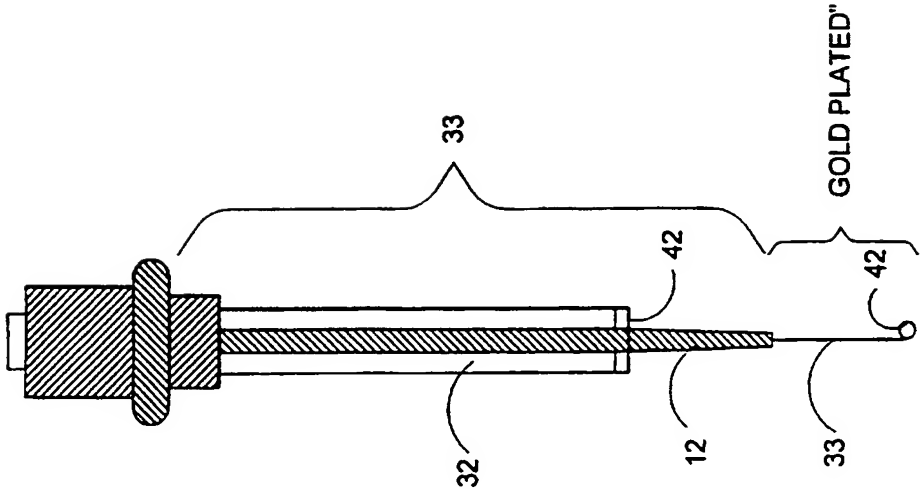

FIG.4

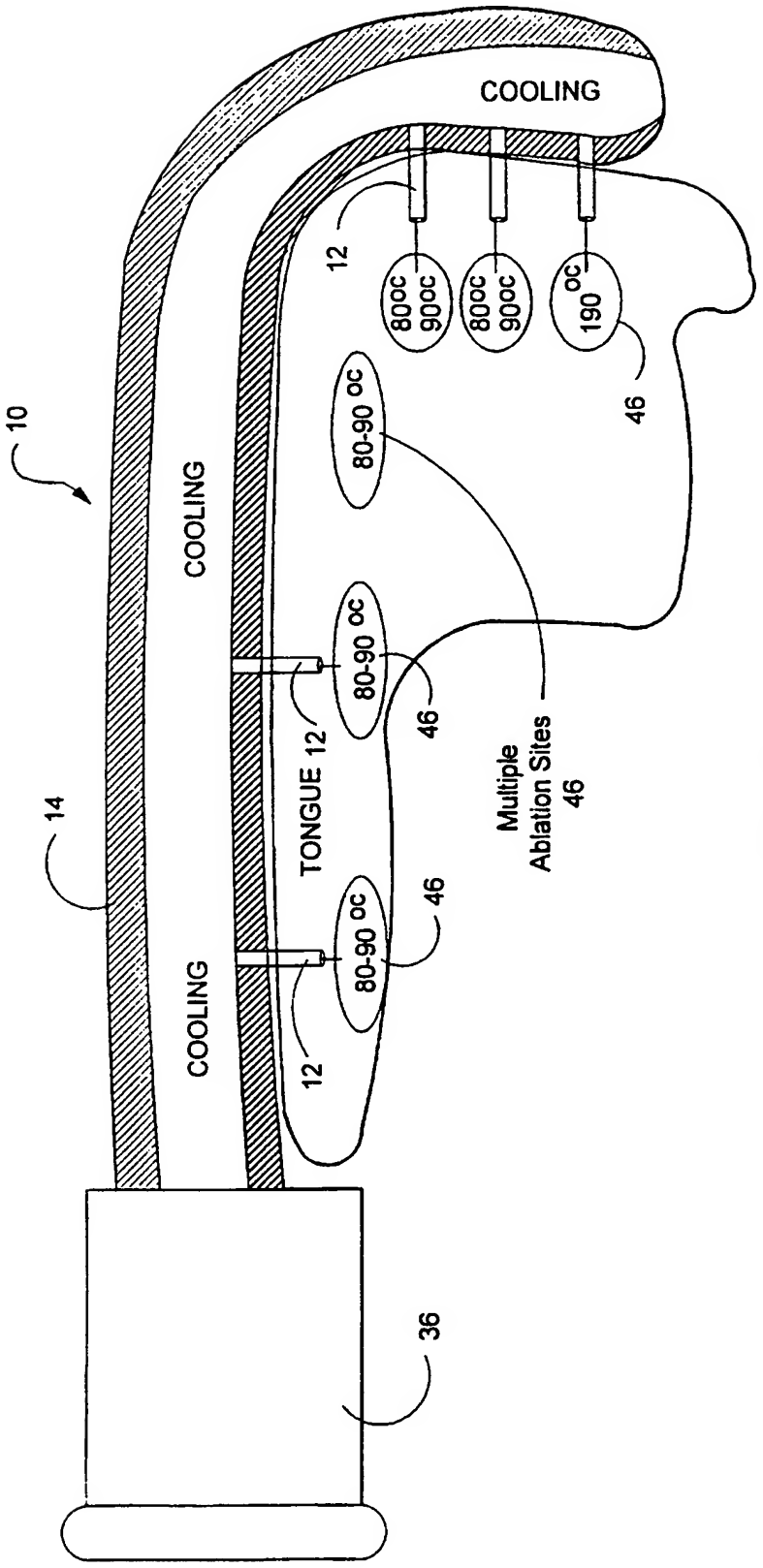
COOLING
12
800c
900c
800c
900c
190 oc
46
10
80-90 oc
COOLING
80-90 oc
46
Multiple
Ablation Sites
46
14
TONGUE 12
80-90 oc
46
COOLING
12
36

FIG.6

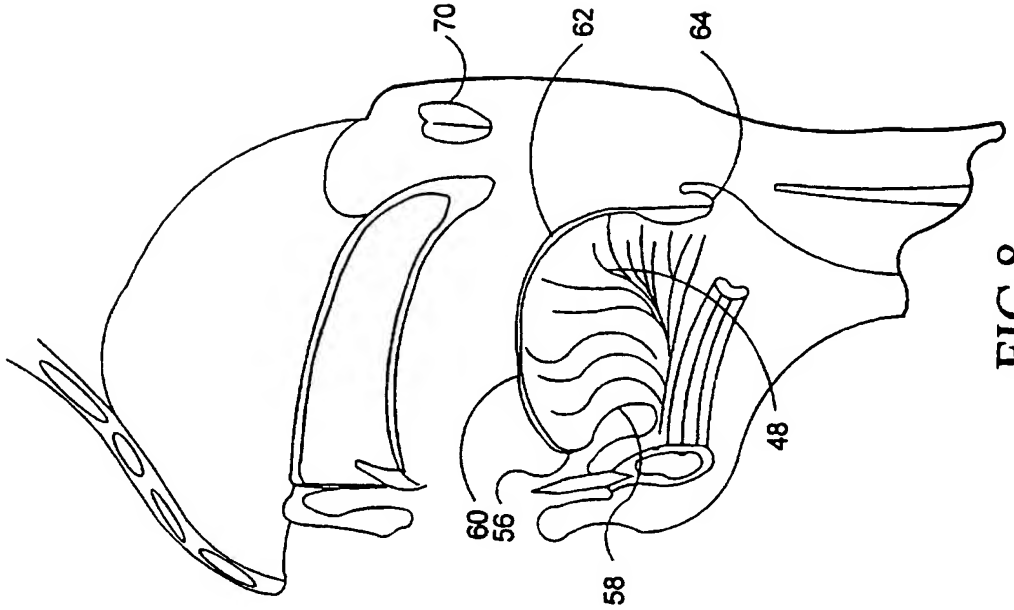

FIG.8

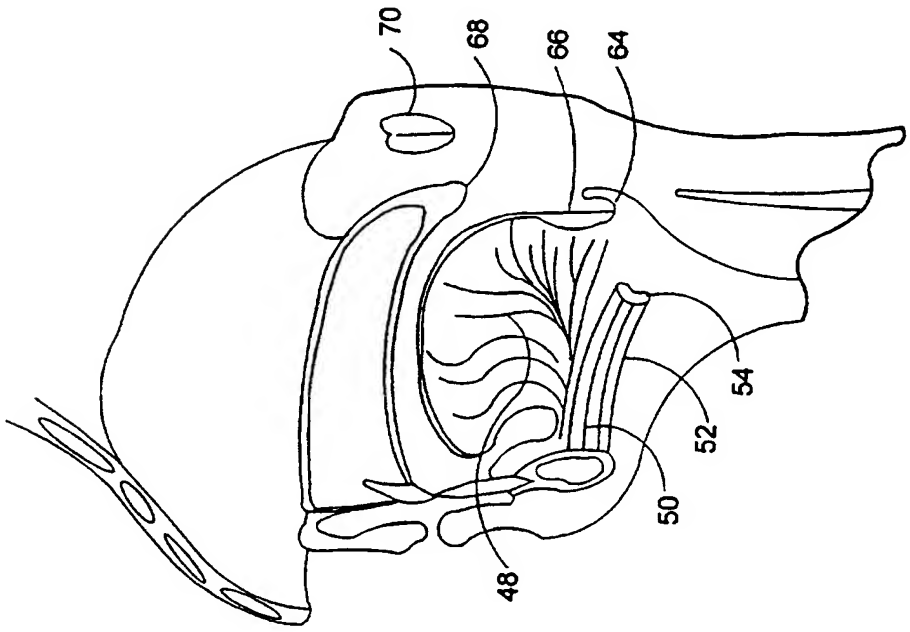

FIG.7

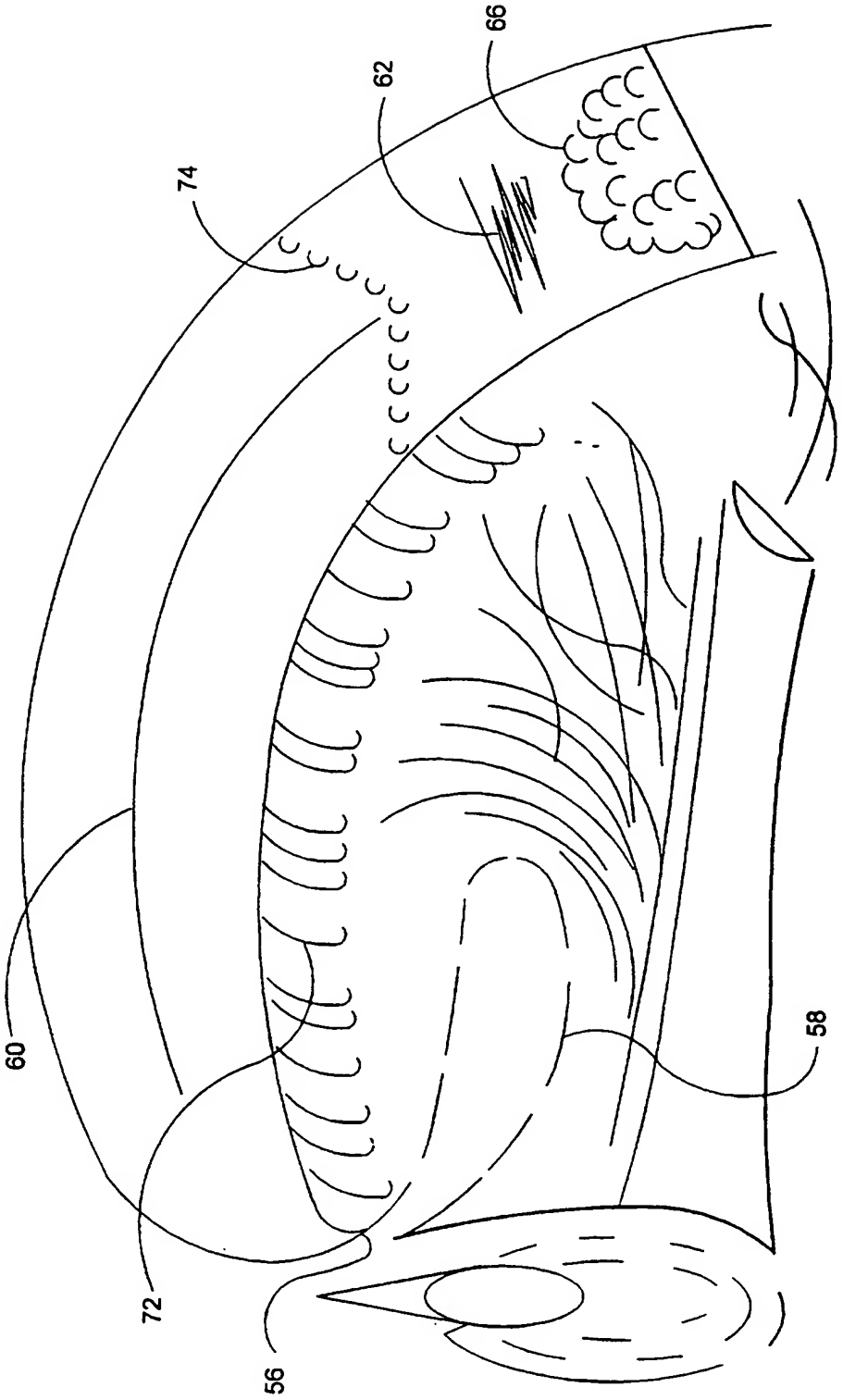

FIG.9

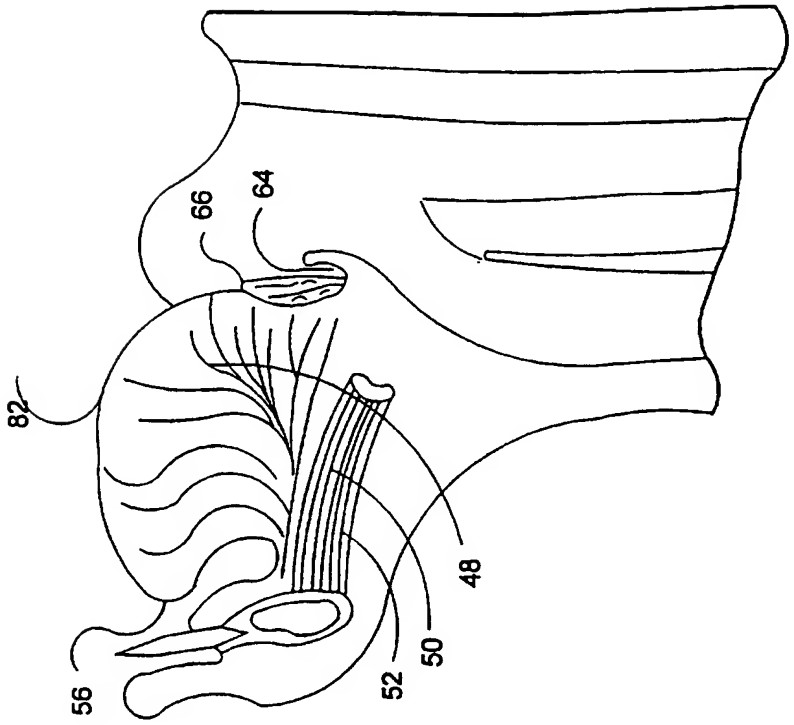

FIG.11

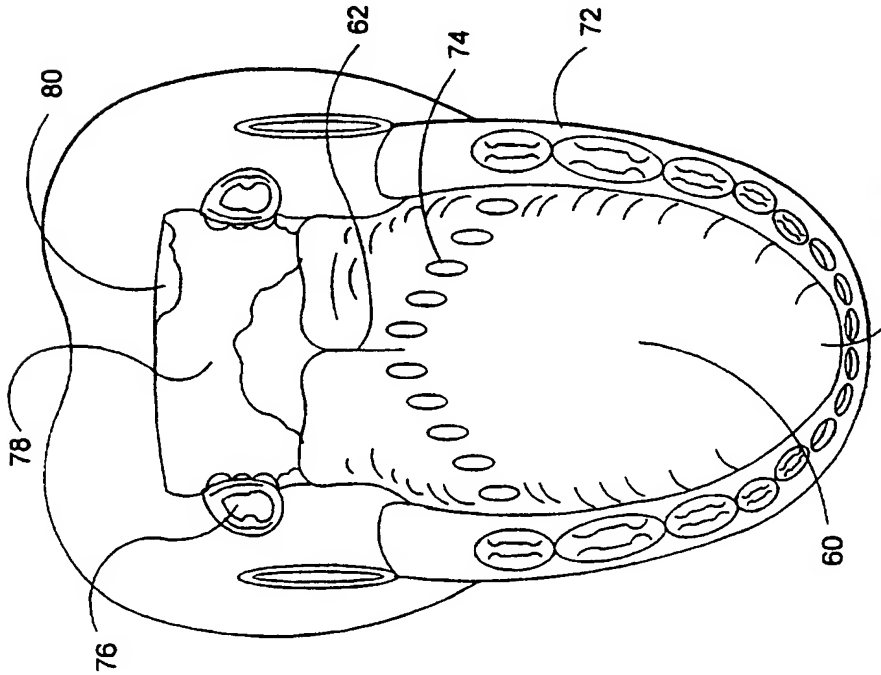

FIG.10

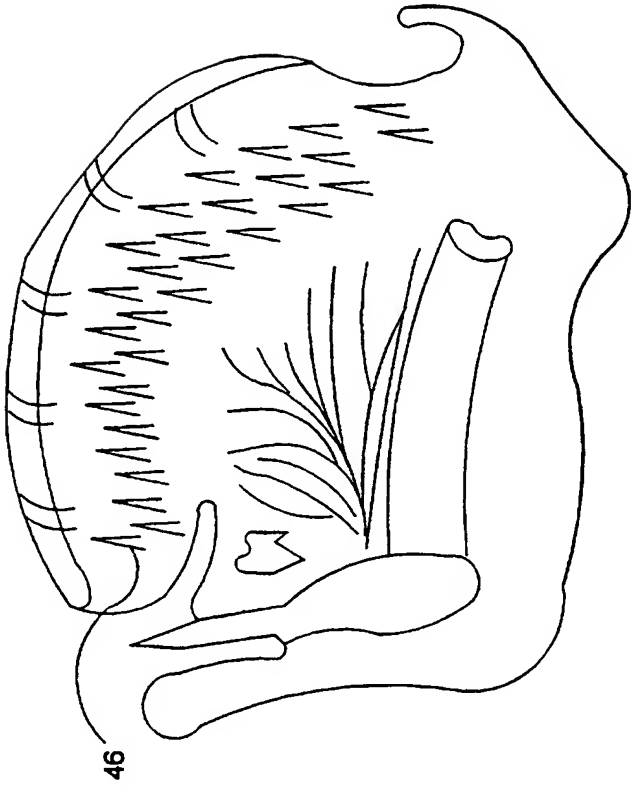

FIG.13

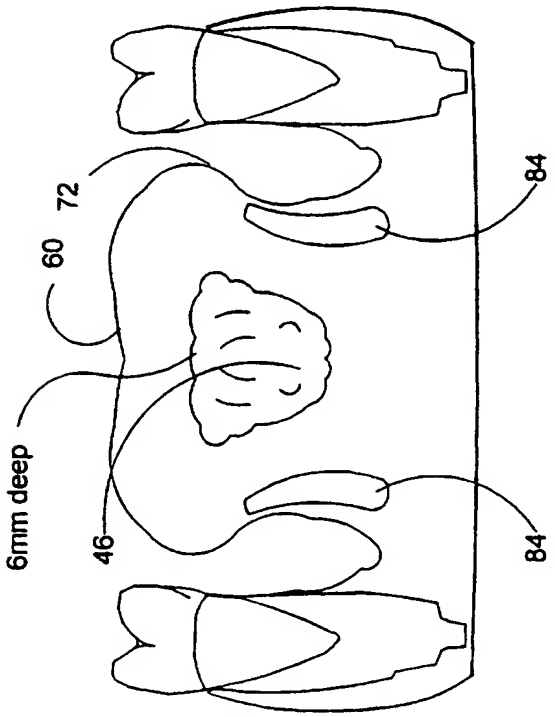

FIG.12

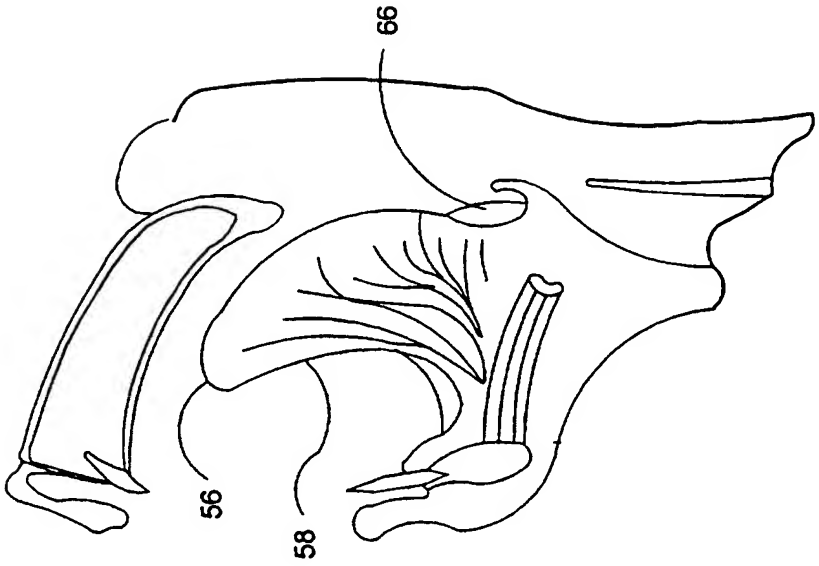

FIG.15

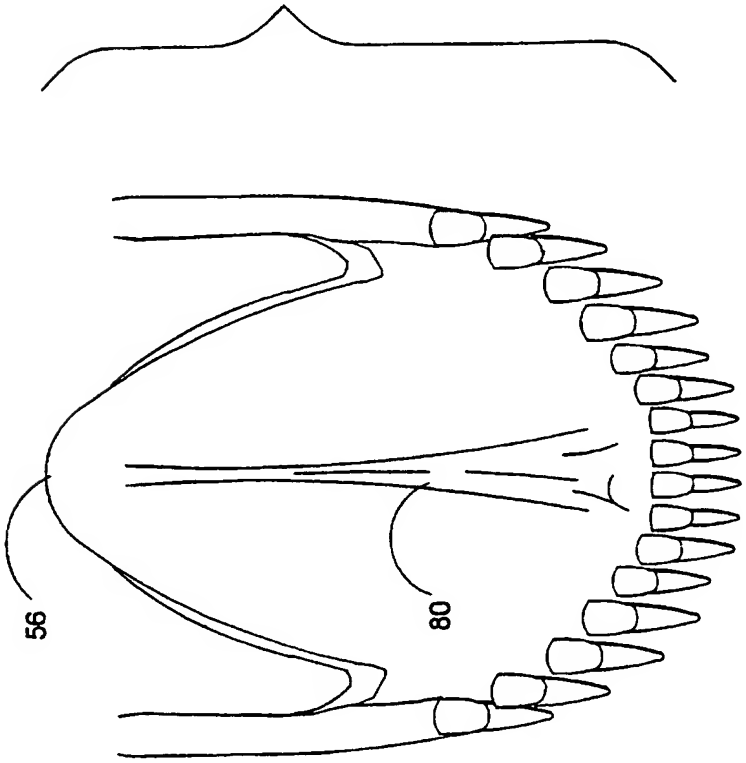

FIG.14

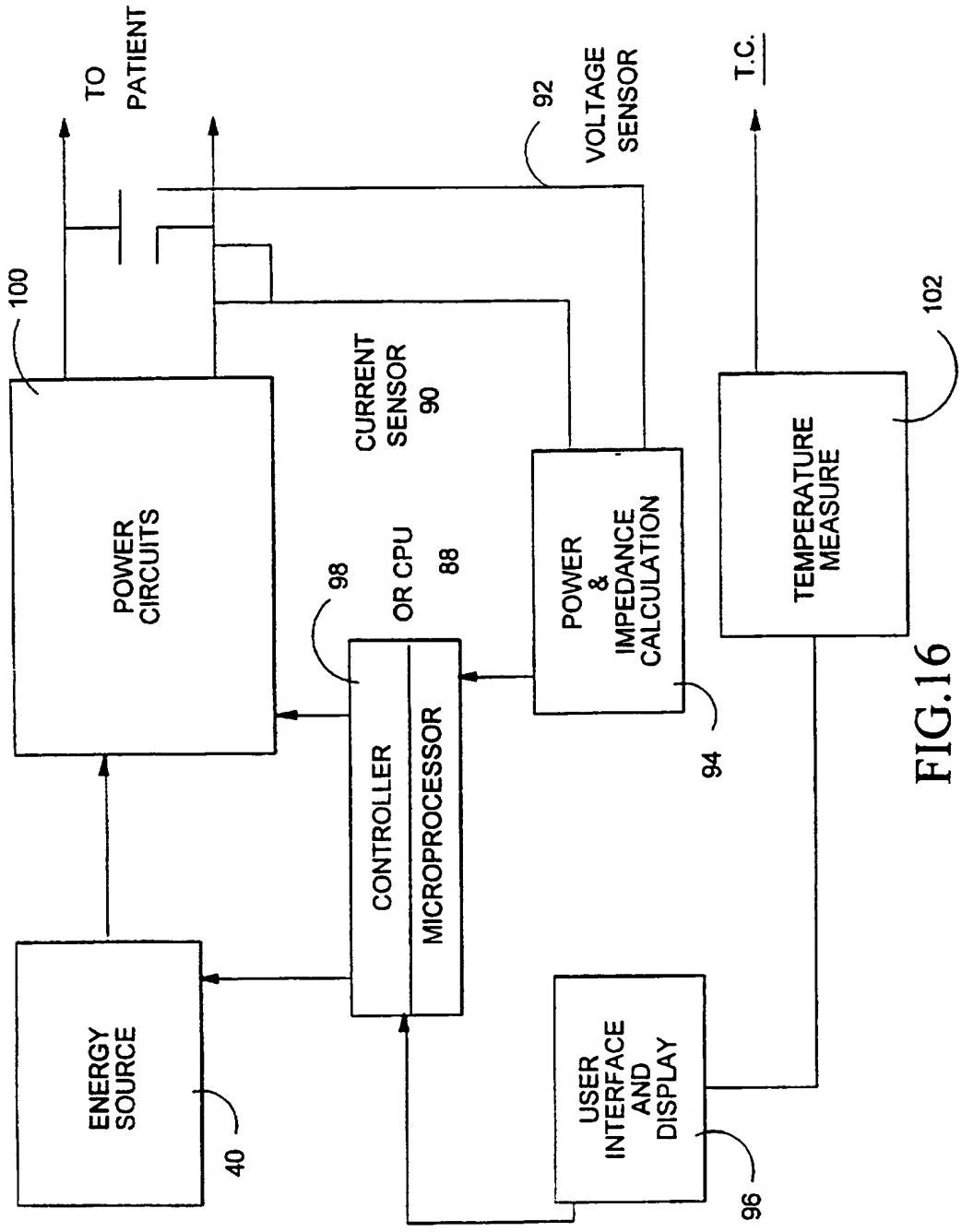
TO PATIENT
92
VOLTAGE SENSOR
T.C.
100
CURRENT SENSOR 90
102
POWER CIRCUITS
98
OR CPU 88
POWER & IMPEDANCE CALCULATION
TEMPERATURE MEASURE
CONTROLLER
MICROPROCESSOR
94
ENERGY SOURCE
40
USER INTERFACE AND DISPLAY
96

FIG.16

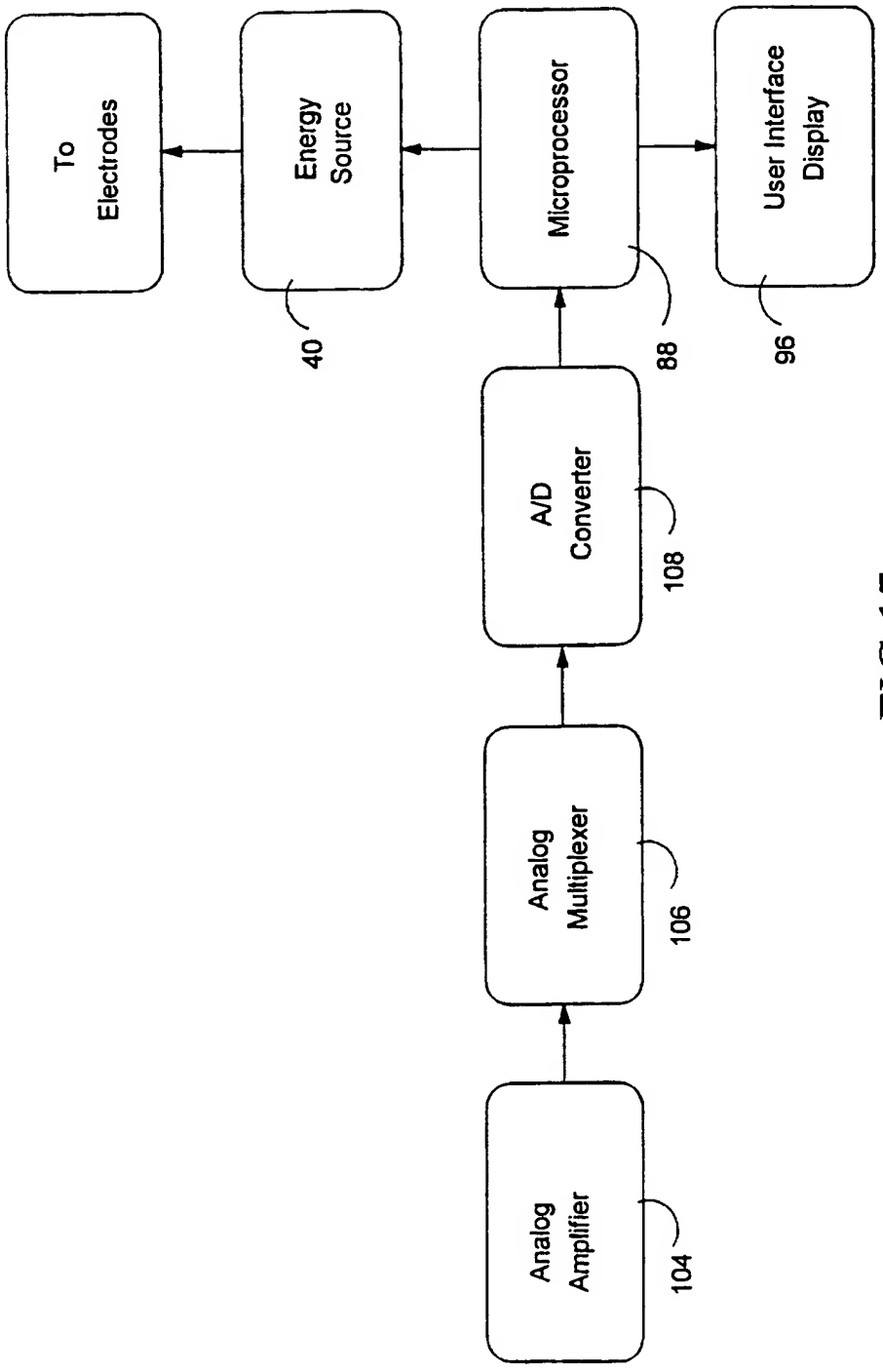
To Electrodes
Energy Source
Microprocessor
User Interface Display
40
88
96
A/D Converter
108
Analog Multiplexer
106
Analog Amplifier
104

FIG.17

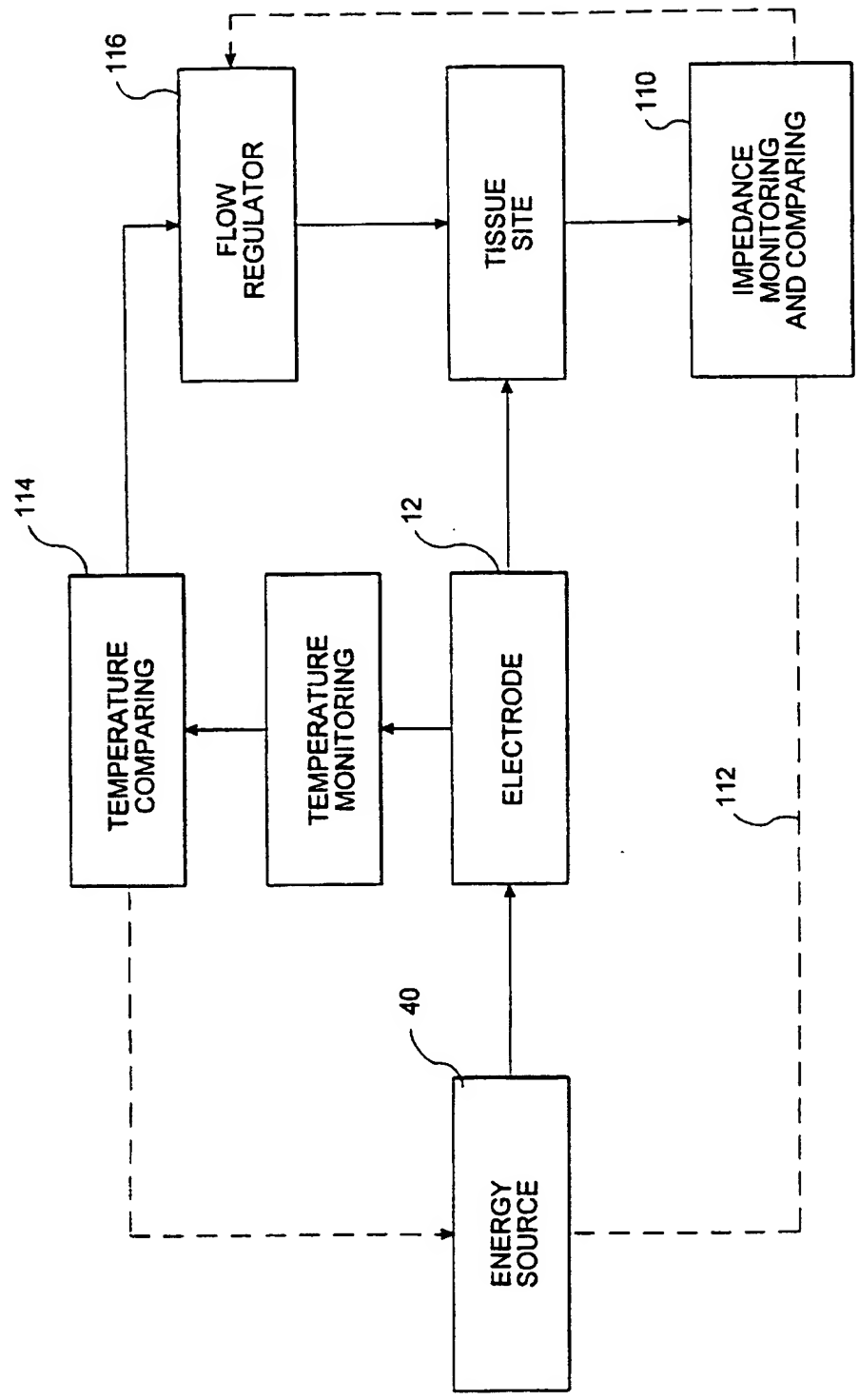
116
FLOW REGULATOR
TISSUE SITE
110
IMPEDANCE MONITORING AND COMPARING
114
12
TEMPERATURE COMPARING
TEMPERATURE MONITORING
ELECTRODE
112
40
ENERGY SOURCE

FIG. 18

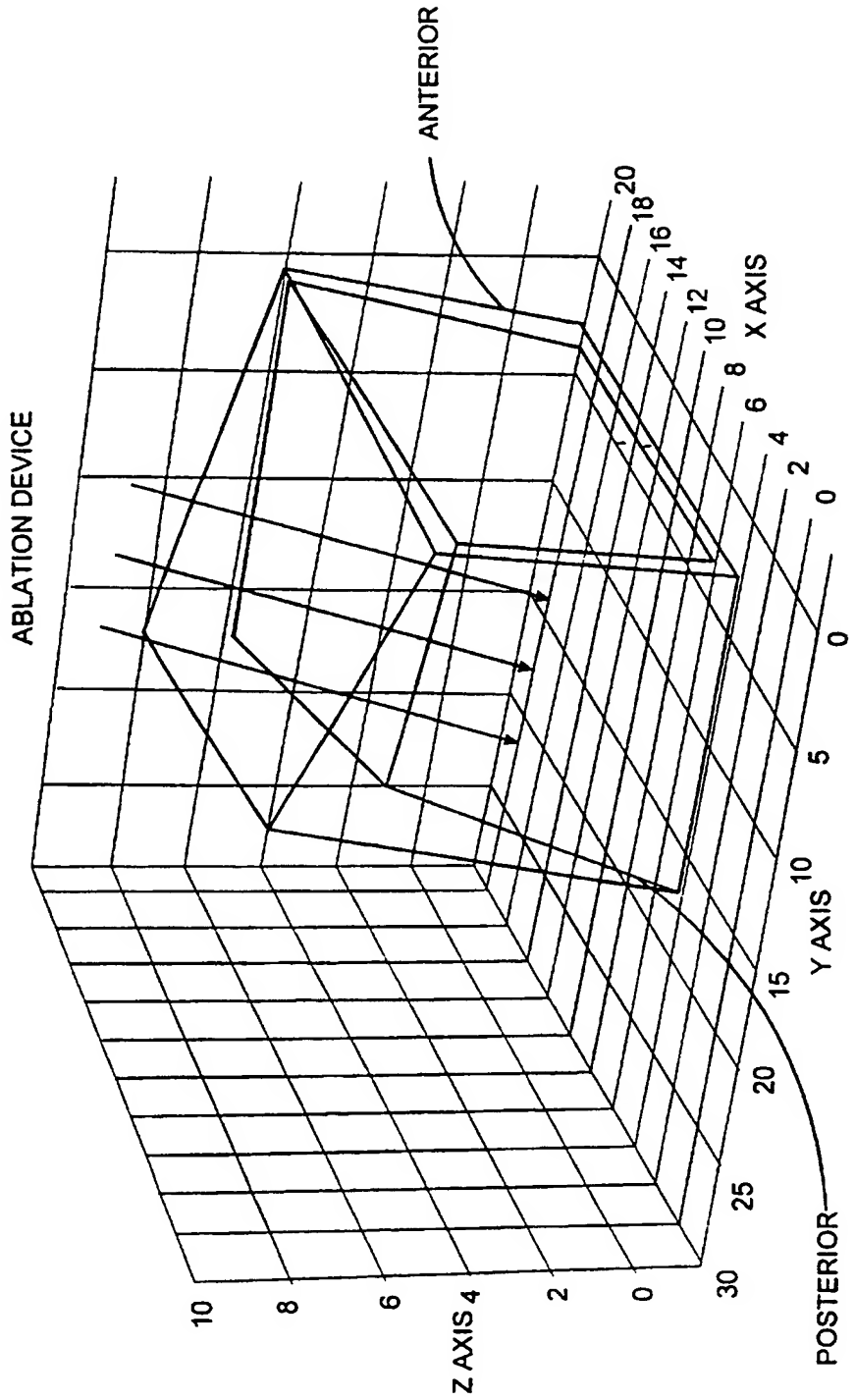
ANTERIOR
ABLATION DEVICE
X AXIS
Y AXIS
Z AXIS
POSTERIOR
AVERAGE SHRINKAGE IN Z DIRECTION = 20%

FIG. 19

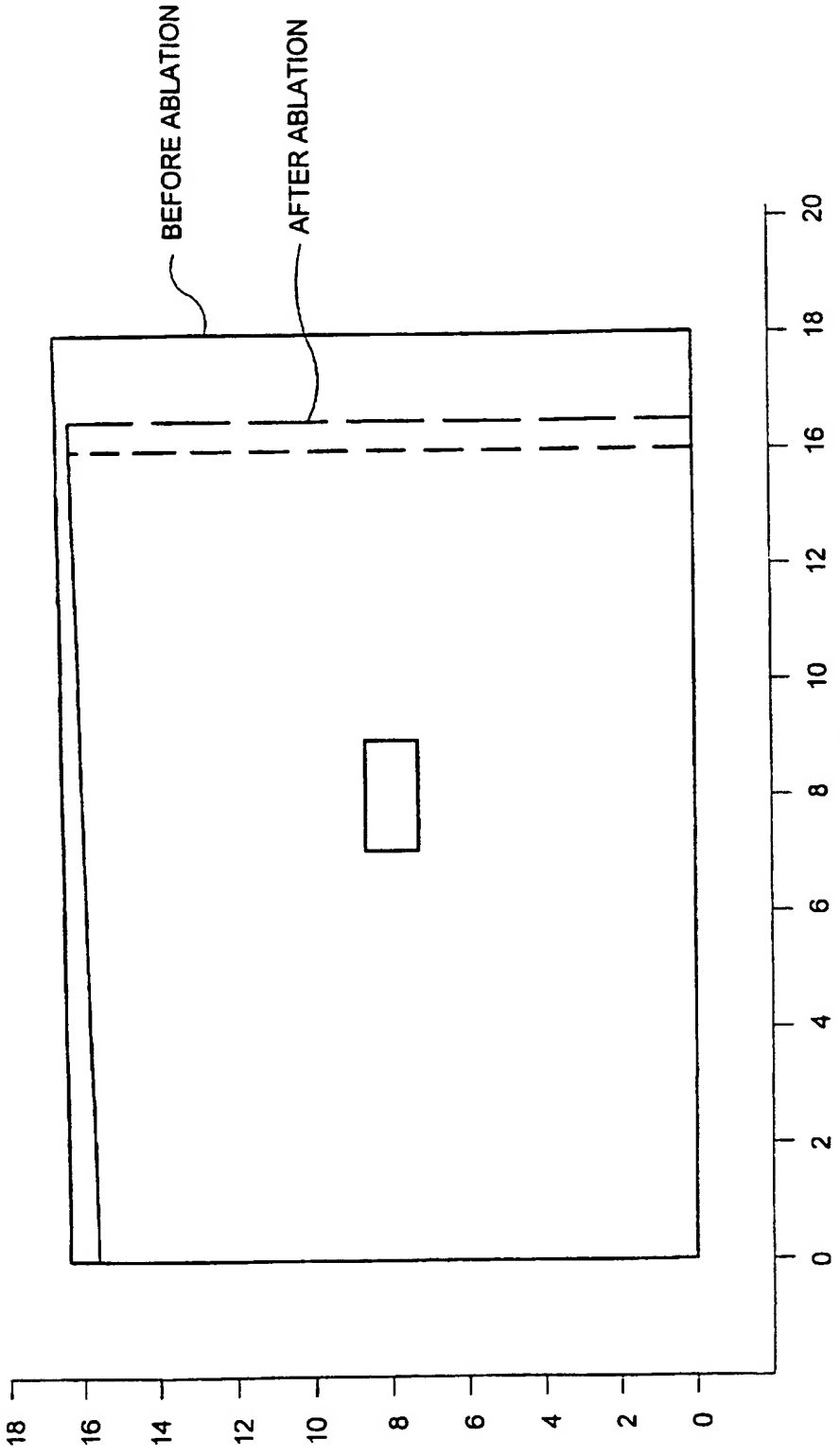
BEFORE ABLATION
AFTER ABLATION
0
2
4
6
8
10
12
14
16
18
0
2
4
6
8
10
12
16
18
20
m m

FIG. 20

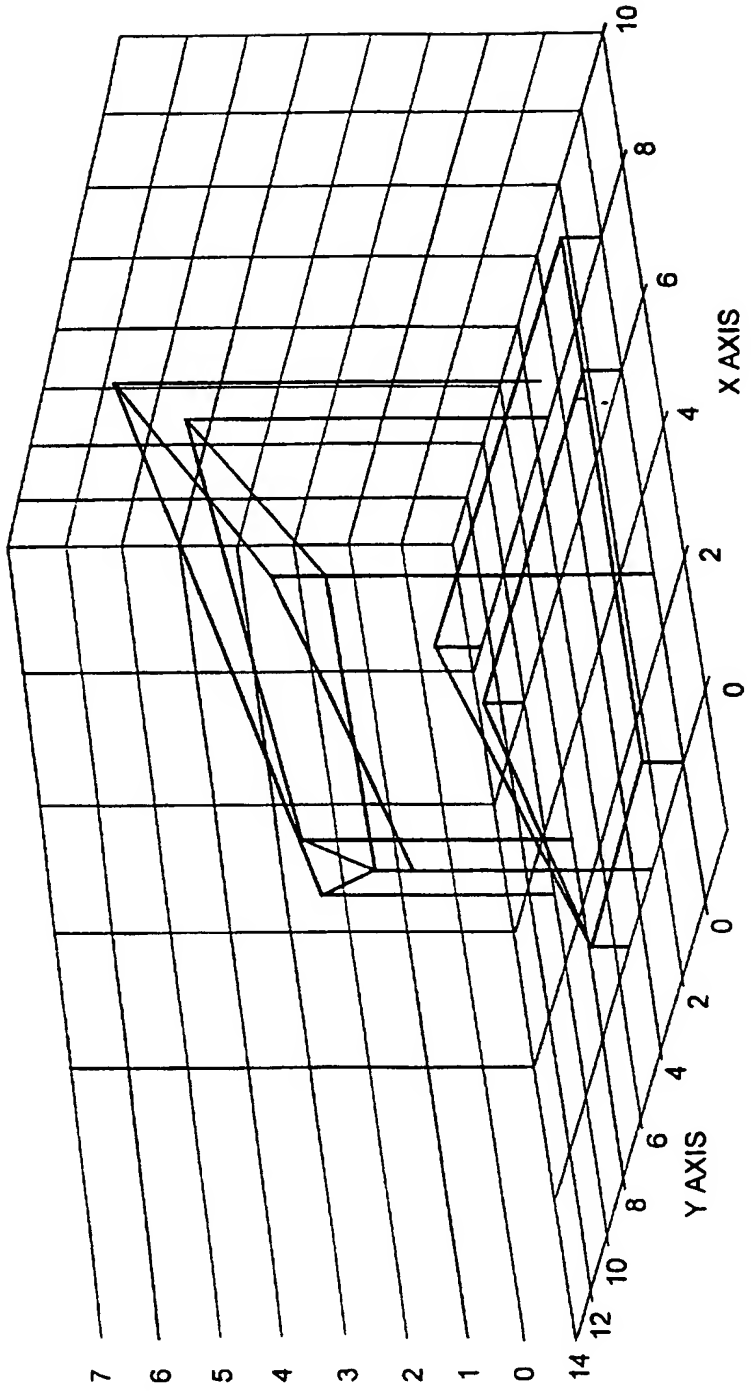

FIG. 21

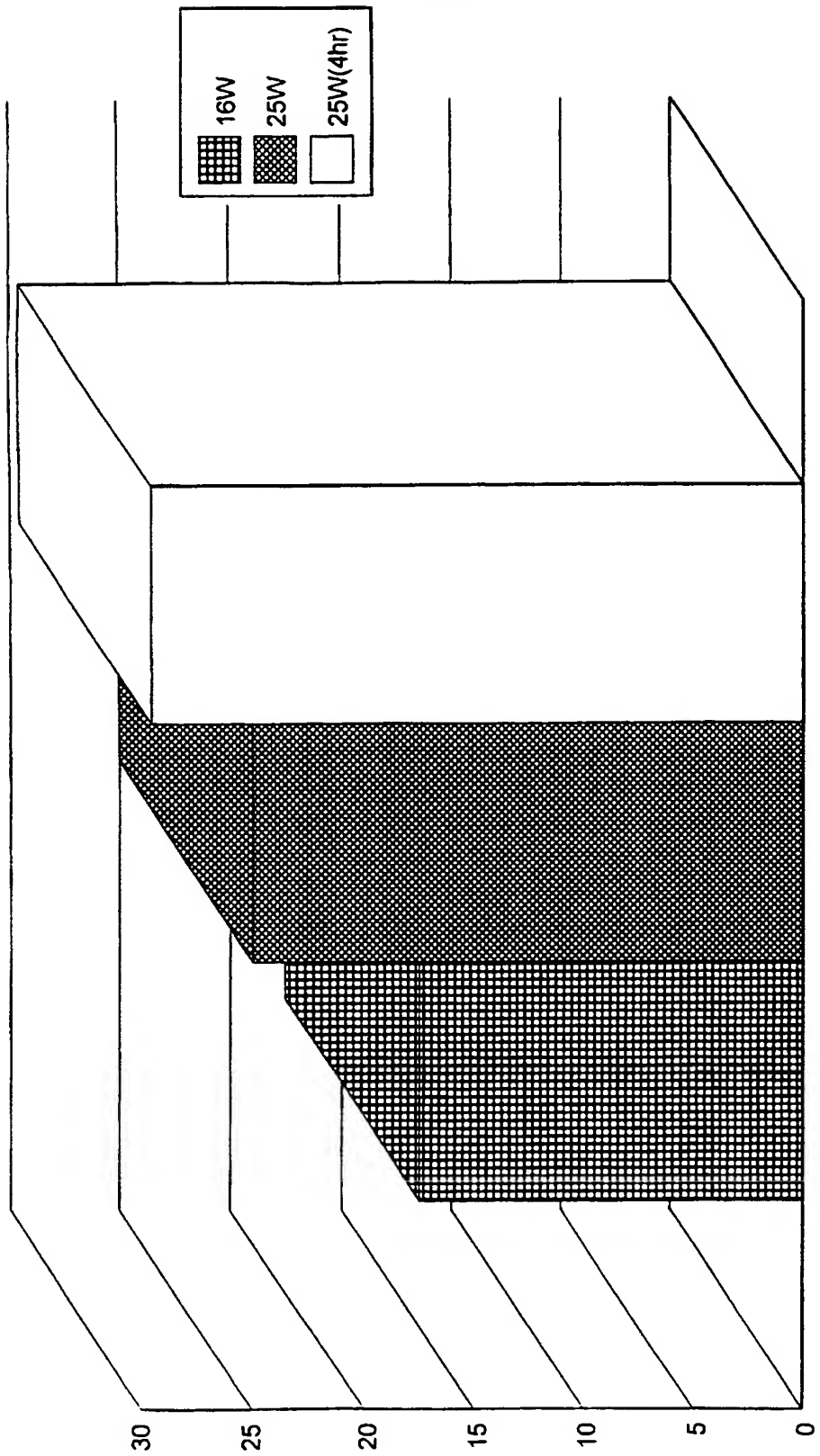

FIG. 22

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 96/13414

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/39 A61N5/04 A61N1/40

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO,A,95 19142 (VIDAMED) 20 July 1995 see abstract; figures 2,3	1,20,27, 42
A	WO,A,95 18575 (VIDAMED) 13 July 1995 see abstract	1
A	EP,A,0 608 609 (CARDIAC PATHWAYS) 3 August 1994 see abstract; figure 1	1
A	US,A,5 334 196 (NARDELLA) 2 August 1994 see abstract; figures 1-4	1
A	EP,A,0 139 607 (YEDA RESEARCH) 2 May 1985 see figures 7,8A	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 December 1996	17. 12. 96

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Papone, F

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Internat l application No.
PCT/US 96/ 13414

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: ALL
because they relate to subject matter not required to be searched by this Authority, namely:
See PCT Rule 39.1 (iv)

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.